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Prior Authorization Guideline

Guideline ID	GL-144743
Guideline Name	Acetaminophen (Dose > 4 gm)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/21/2024

1 . Criteria

Product Name: Acetaminophen (Dose > 4gm)	
Diagnosis	DUR Reject 88 (Total APAP > 4 g)
Guideline Type	DUR Reject 88
Approval Criteria **1** - Requests for acetaminophen dosages greater than 4000mg per day should be denied. The total dose of acetaminophen (cumulative total daily dose of 4000mg) is not supported by the Food and Drug Administration (FDA).	
Notes	Note: Reject message: "DUR1:APAP = Total APAP >4g; Verify dose; EnterO/R -"

2 . Revision History

Date	Notes
3/21/2024	Guideline type changed from Administrative to DUR Reject 88

Prior Authorization Guideline

Guideline ID	GL-123416
Guideline Name	Actemra - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/18/2023

1 . Criteria

Product Name: Actemra IV, Actemra SQ	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of moderately to severely active Rheumatoid Arthritis (RA)

AND

1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is not receiving Actemra in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)**
- Enbrel (etanercept)**

AND

1.5 Prescribed by, or in consultation with, a rheumatologist

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is not receiving Actemra in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by, or in consultation with, a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Drug may require PA

Product Name: Actemra IV, Actemra SQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to both of the following:

- Humira (adalimumab)*

- Enbrel (etanercept)*

OR

2.2 Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by, or in consultation with, a rheumatologist

Notes	*May require PA

Product Name: Actemra IV, Actemra SQ	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra IV, Actemra SQ	
Diagnosis	Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis (PJIA), Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

2 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra IV, Actemra SQ

Diagnosis	Giant Cell Arteritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of giant cell arteritis

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to ONE glucocorticoid (e.g., prednisone)

OR

2.2 Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Diagnosis	Giant Cell Arteritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

2 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra SQ	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of active systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs

AND

2 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a pulmonologist

Product Name: Actemra SQ	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

2 - Patient is not receiving Actemra in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a pulmonologist

Product Name: Actemra IV	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of COVID-19

AND

2 - Patient is hospitalized (Actemra is only FDA approved when used for COVID 19 patients in an inpatient setting)

AND

3 - Currently receiving systemic corticosteroids

AND

4 - Patient requires one of the following:

- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation
- Extracorporeal membrane oxygenation (ECMO)

Notes	NOTE: Actemra is only FDA approved when used for COVID 19 patients in an inpatient setting

2 . Revision History

Date	Notes
3/17/2023	Added note to COVID 19 indication, no change to clinical criteria.

Prior Authorization Guideline

Guideline ID	GL-102899
Guideline Name	Acthar Gel, Cortrophin Gel
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Acthar Gel	
Diagnosis	Infantile spasm (i.e., West Syndrome)*
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile spasms (i.e., West Syndrome)*

AND

2 - Patient is less than 2 years old

AND

3 - Both of following:

3.1 Initial dose: 75 units per meters squared intramuscular (IM) twice daily for 2 weeks

AND

3.2 After 2 weeks, dose should be tapered according to the following schedule: 30 units per meters squared IM in the morning for 3 days; 15 units per meters squared IM in the morning for 3 days; 10 units per meters squared IM in the morning for 3 days; 10 units per meters squared IM every other morning for 6 days (3 doses)

Notes	*Note: Acthar Gel is not medically necessary for treatment of acute ex acerbations of multiple sclerosis.

Product Name: Acthar Gel, Cortrophin	
Diagnosis	Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*

AND

2 - For Cortrophin requests ONLY: Trial and failure or intolerance to Acthar Gel (verified via paid pharmacy claims or submission of medical records/chart notes)

Notes	*Note: Acthar Gel is not medically necessary for treatment of acute ex acerbations of multiple sclerosis.

2 . Revision History

Date	Notes
2/3/2022	Added step through Acthar to get Cortrophin [for OMS Syndrome crit eria (not indicated for infantile spasms)]

Prior Authorization Guideline

Guideline ID	GL-99673
Guideline Name	Actimmune
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic granulomatous disease	

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, malignant osteopetrosis

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Actimmune will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Actimmune therapy

2 . Revision History

Date	Notes
6/7/2021	7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124866
Guideline Name	Adacel TDAP vaccine
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Adacel	
Diagnosis	Pregnant Patients 19 years of age and older*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

2 - Vaccine is being used to prevent pertussis in infants younger than 2 months of age

AND

1 - Patient is 19 years of age or older

AND **3** - Both of the following: • Patient is pregnant • Vaccine is being administered during 3rd trimester of pregnancy	
Notes	*Note: Patients under 19 years of age must get immunization from PCP or pediatrician through the VFC (Vaccines For Children) Program

2 . Revision History

Date	Notes
4/20/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99677
Guideline Name	Adakveo
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Adakveo	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sickle cell disease, identified by any genotype

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Age 16 to 20 years
- Prescriber attests the service is medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness in an eligible patient

OR

2.2 Age greater than or equal to 21 years

AND

3 - Patient has experienced at least two vaso-occlusive crises within the past 12 months

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-141160
Guideline Name	Adbry (tralokinumab-ldrm)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/7/2024

1 . Criteria

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	6 Months*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Submission of documentation (e.g., chart notes) demonstrating one of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - History of failure, contraindication, or intolerance to BOTH of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)**

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole) ointment

Notes	*QL Override (For new starts only): Enter 2 PAs as follows: First PA: Approve 6 syringes per 28 days for one month; Second PA: Approve 4 syringes per 28 days (no overrides needed) for the remaining 11 mo nths. (Adbry is hard-coded with a quantity of 4 syringes per 28 days). **Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) demonstrating positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05

	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes

2/6/2024	Removed step through Dupixent

Prior Authorization Guideline

Guideline ID	GL-136984
Guideline Name	ADHD Agents - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Brand Adderall, generic amphetamine/dextroamphetamine tablets, Brand Adderall XR, generic amphetamine/dextroamphetamine ER capsules, Brand Aptensio XR, generic atomoxetine, Brand Concerta, Brand Daytrana, generic dexmethylphenidate tablets, generic dexmethylphenidate ER, generic dextroamphetamine tablets, Brand Focalin, Brand Focalin XR, generic lisdexamfetamine capsules and chewables, Brand Methylin solution, generic methylphenidate solution, generic methylphenidate tablets, generic methylphenidate ER tablets, generic methylphenidate ER (CD) capsules, generic methylphenidate ER (LA) capsules, generic methylphenidate ER (XR) capsules, generic methylphenidate patch, Brand Ritalin, Brand Ritalin LA, Brand Strattera, Brand Vyvanse capsules and chewables, Brand Zenzedi	
Diagnosis	PA Required for Children Under 6 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications

AND

3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications

AND

4 - The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

Product Name: Brand Intuniv, generic guanfacine IR/ER, Brand Kapvay, generic clonidine IR/ER	
Diagnosis	PA Required for Children Under 6 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

1.1.2 The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications

AND

1.1.3 The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications

AND

1.1.4 The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

OR

1.2 Both of the following:

1.2.1 Diagnosis of insomnia

AND

1.2.2 Trial and failure, contraindication, or intolerance to melatonin

Product Name: NON-PREFERRED DRUGS: Xelstrym patch	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a history of failure, contraindication, or intolerance to a trial to THREE of the following preferred products*:

- Brand Adderall
- generic amphetamine/dextroamphetamine tablets
- Brand Adderall XR
- Brand Concerta ER
- generic dexmethylphenidate tablets
- Brand Focalin XR
- Brand Methylin solution
- generic methylphenidate tablets
- Brand Ritalin LA
- generic methylphenidate ER (CD) capsules
- Vyvanse capsules
- generic atomoxetine
- generic clonidine ER
- generic guanfacine ER
- generic dextroamphetamine tablets

AND

2 - The patient has a history of failure, contraindication, or intolerance to Daytrana

Notes	*Alternatives may require prior authorization

Product Name: NON-PREFERRED DRUGS: Brand Adhansia XR, Brand Adzenys XR-ODT, generic amphetamine IR tablets, generic amphetamine ER suspension, generic amphetamine/dextroamphetamine ER capsules, Brand Aptensio XR, Brand Azstarys, Brand Cotempla XR-ODT, Brand Desoxyn, Brand Dexedrine, generic dextroamphetamine oral solution, generic dextroamphetamine IR tablet, generic dextroamphetamine ER, Brand Dyanavel XR (oral suspension and chewable tablets), Brand Evekeo, Brand Evekeo ODT, Brand Focalin, Brand Focalin XR, Brand Intuniv, Brand Jornay PM, Brand Kapvay, generic lisdexamfetamine capsules and chewables, generic methamphetamine , generic methylphenidate chewable, generic methylphenidate patch, generic methylphenidate soln, generic methylphenidate ER tablets, generic methylphenidate ER (LA) capsules, generic methylphenidate ER (XR) capsules, Brand Mydayis, Brand Procentra, Brand Qelbree, Brand Quillichew ER, Brand Quillivant XR, Relexxii, Brand Ritalin, Brand Strattera, Brand Vyvanse chewables, Brand Zenzedi

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a history of failure, contraindication, or intolerance to a trial to FOUR of the following preferred products*: • Brand Adderall • generic amphetamine/dextroamphetamine tablets • Brand Adderall XR • Brand Concerta ER • Daytrana • generic dexmethylphenidate tablets • Brand Focalin XR • Brand Methylin solution • generic methylphenidate tablets • Brand Ritalin LA • generic methylphenidate ER (CD) capsules • Vyvanse capsules • generic atomoxetine • generic clonidine ER • generic guanfacine ER • generic dextroamphetamine tablets	
Notes	*Alternatives may require prior authorization

2 . Revision History

Date	Notes
11/28/2023	Added new GPIs for Relexxii

Prior Authorization Guideline

Guideline ID	GL-133805
Guideline Name	Adstiladrin (nadofaragene firadenovec-vncg)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Adstiladrin	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of high-risk, non-Muscle Invasive Bladder Cancer (NMIBC)

AND

1.2 One of the following:

- Tumor is carcinoma in situ (CIS)
- Ta/T1 high grade disease

AND

1.3 Patient is not eligible for or has elected not to undergo cystectomy

AND

1.4 Patient has received an adequate course of Bacillus Calmette Guérin (BCG) therapy defined as the administration of at least 5 of 6 doses of an initial induction course plus one of the following:

- At least two of three doses of maintenance therapy
- At least two of six doses of a second induction course

AND

1.5 Tumor is BCG unresponsive as defined by one of the following:

- Persistent disease following adequate BCG therapy
- Disease recurrence after an initial tumor-free state following adequate BCG therapy
- T1 disease following a single induction course of BCG

AND

1.6 The patient has had all resectable disease (Ta and T1 components) removed

AND

1.7 The patient does not have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma

Product Name: Adstiladrin

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

2 . Revision History

Date	Notes
9/26/2023	New Program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-107262
Guideline Name	Aduhelm (aducanumab-avwa)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/17/2022

1 . Criteria

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - MEDICARE PART B*
Approval Length	6 month(s)
Guideline Type	Medicare Part B

Approval Criteria

1 - Requested medication is billed through Medicare Part B

AND

2 - Submission of documentation confirming patient is enrolled in a CMS approved prospective comparative study

Notes	*Note: THIS SECTION SHOULD ONLY BE USED FOR DUAL ELIGIB LE MEMBERS (WILL HAVE AZMDUAL PLAN CODE) COVERED UN DER MEDICARE PART B THAT ARE REQUESTING SECONDARY COVERAGE.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - MEDICARE PART D*
Approval Length	None
Guideline Type	Prior Authorization requests from providers from Medicare Part D for Dual Eligible Members

Approval Criteria

1 - Requested medication is billed through Medicare Part D

AND

2 - Requests for coverage of Aduhelm (aducanumab) are not authorized and will not be approved under Part D

Notes	*Note: THIS SECTION SHOULD ONLY BE USED FOR DUAL ELIGIB LE MEMBERS (WILL HAVE AZMDUAL PLAN CODE). APPROVAL L ENGTH: NONE - REQUESTS FOR ADUHELM ARE NOT COVERED UNDER MEDICARE PART D AND SHALL BE DENIED AS A BENEF IT EXCLUSION.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - FEE-FOR-SERVICE
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Mild cognitive impairment (MCI) due to Alzheimer's Disease (AD)
- Mild dementia due to Alzheimer's Disease (AD)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values, examination histories) documenting the basis for diagnosis, including all of the following:

2.1 Documentation of a comprehensive history and neurological examination, inclusive of a description of the nature and duration of cognitive symptoms within the previous 3 months

AND

2.2 Medical records documenting baseline (within the previous three months) cognitive function based on ONE of the following objective assessments:

- Mini-Mental State Examination (MMSE) score ≥ 24
- Montreal Cognitive Assessment (MoCA) score ≥ 15

AND

2.3 Medical records documenting confirmed evidence of clinically significant AD neuropathology based on ONE of the following:

- Cerebral Spinal Fluid (CSF) biomarkers
- Amyloid positron emission tomography (PET)

AND

3 - Patient has received recent (within the previous 3 months) baseline brain magnetic resonance imaging (MRI) prior to initiating treatment

AND

4 - Patient does not have significant cerebrovascular disease as established by brain MRI showing any of the following:

- Acute or sub-acute hemorrhage
- Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage)
- 4 or more brain microhemorrhages
- Cortical infarct
- More than 1 lacunar infarct
- Superficial siderosis
- History of diffuse white matter disease

AND

5 - Patient does not have any of the following non-AD neurodegenerative disorders:

- Probable dementia with Lewy bodies by consensus criteria
- Suspected frontotemporal degeneration
- Dementia in down syndrome

AND

6 - Patient does not have any of the following exclusionary neurological or psychiatric conditions:

- Uncontrolled seizure disorder
- Uncontrolled mood disorder, anxiety disorder, or psychosis
- Substance use disorder active in the past 2 years

AND

7 - Patient does not have any of the following cardiovascular conditions:

- Uncontrolled hypertension
- Coronary artery disease (including unstable angina and myocardial infarction)
- Heart failure
- Arrhythmia
- Clinically significant carotid atherosclerosis and/or peripheral arterial disease

AND

8 - Both of the following:

- Patient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less)
- Patient has no history of transient ischemic attack (TIA), stroke, or unexplained loss of consciousness within previous year prior to initiating treatment

AND

9 - Patient does not have any uncontrolled clinically significant chronic medical condition (e.g., liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection [HIV, HCV], poorly controlled diabetes mellitus)

AND

10 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

11 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatrics specialist

AND

12 - Prescriber attests that the patient and/or authorized representative (e.g., power of attorney, invoked health care proxy) has shared in decision-making and has been informed on the known and potential risks and lack of established clinical benefit associated with Aduhelm (aducanumab-avwa) treatment

AND

13 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had ≥ 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)

• If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity] • If the patient has had ≥ 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied	
Notes	*NOTE: If the patient has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. *NOTE: If the patient had a serious event, therapy should be discontinued. † *NOTE: If the patient has had ≥3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. †Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity. ‡Requests should be evaluated case-by-case with clinical review and MD advisor.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - FEE-FOR-SERVICE
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

2 - Follow-up MRIs have been conducted at the following timeframes:

- Week 14 (after 4th infusion, prior to first 6 mg/kg dose)
- Week 22 (after 6th infusion, prior to first 10 mg/kg dose)
- Week 30 (after 8th infusion, prior to third 10 mg/kg dose)

- Week 42 (after 11th infusion, prior to sixth 10 mg/kg dose)
- Every 6 months thereafter

AND

3 - Patient's diagnosis continues to be mild cognitive impairment or mild dementia stage due to Alzheimer's disease as established by one of the following examination scales:

3.1 One of the following:

- Mini Mental State Exam (MMSE) score ≥ 24
- Montreal Cognitive Assessment (MoCA) score ≥ 15

OR

3.2 Both of the following:

- MMSE <24 or MoCA <15
- Rate of decline was slower than expected (<2 points/year)

AND

4 - ONE of the following (ARIA-H, microhemorrhages):

- Patient has had no new incident microhemorrhage
- Patient has had 1 to 4 new incident microhemorrhage(s) AND microhemorrhages are asymptomatic (no clinical symptoms)
- Patient has had 5 to 9 new incident microhemorrhages AND microhemorrhages are asymptomatic (no clinical symptoms) AND the microhemorrhages have been stabilized
- Patient has had 1 to 9 new incident microhemorrhages AND microhemorrhages resulted in mild, moderate or severe clinical symptoms AND the microhemorrhages have been stabilized

AND

5 - ONE of the following (ARIA-H, superficial siderosis)

- Patient has had no new incident areas of superficial siderosis
- Patient has had 1 new incident area of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms)

- Patient has had 2 new incident areas of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms) AND the superficial siderosis has been stabilized
- Patient has had 1 to 2 new incident areas of superficial siderosis AND superficial siderosis resulted in mild, moderate or severe clinical symptoms AND the superficial siderosis has been stabilized

AND

6 - ONE of the following (ARIA-E)

- Patient has had no new ARIA-E
- Patient has mild ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms)
- Patient has had moderate or severe ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms) AND the ARIA-E is stable
- Patient has had mild, moderate or severe ARIA-E on MRI AND ARIA-E resulted in mild, moderate or severe clinical symptoms AND the ARIA-E is stable

AND

7 - One of the following:

7.1 Patient does not meet ANY of the following:

- Initiation of anticoagulation
- Development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, SLE, aplastic anemia, myasthenia gravis, meningitis/encephalitis)
- Initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine)
- Development of other neurologic conditions (e.g., intracerebral bleeds, TBI, stroke)

OR

7.2 BOTH of the following:

- Patient does meet one of the above
- Prescriber documents clinical rationale for continued use of aducanumab‡

AND

8 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatric specialist

AND

9 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had ≥ 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)
- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]
- If the patient has had ≥ 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

Notes	*NOTE: If the patient has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. *NOTE: If the patient had a serious event, therapy should be discontinued. † *NOTE: If the patient has had ≥3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. †Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity. ‡Requests should be evaluated case-by-case with clinical review and MD advisor.

2 . Background

Clinical Practice Guidelines	
Appendix **ARIA - H (Microhemorrhages)**	
	New Incident Microhemorrhages

		Radiographic Severity		
		Mild (1 to 4)	Moderate (5 to 9)	Severe (≥10)
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		Stop Permanently
	Moderate			
	Severe			
	Serious	Stop Permanently		

ARIA - H (Superficial Siderosis)

		New Incident Areas of Superficial Siderosis (Central Read)		
		Radiographic Severity		
		Mild (1)	Moderate (2)	Severe (≥3)
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		Stop Permanently
	Moderate			
	Severe			
	Serious	Stop Permanently		

ARIA - E

		ARIA-E Severity on MRI (Central Read)		
		Radiographic Severity		
		Mild	Moderate	Severe
Clinical Sympto	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	

m Severity	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved
	Moderate	
	Severe	
	Serious	Stop Permanently

3 . Revision History

Date	Notes
5/17/2022	Updated Medicare sections for clarification.

Prior Authorization Guideline

Guideline ID	GL-143519
Guideline Name	Adzynma (ADAMTS13, recombinant-krhn)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Adzynma	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP)

AND

1.2 Molecular genetic testing confirms mutations in the ADAMTS13 gene

AND

1.3 Trial and inadequate response, contraindication or intolerance to plasma-based infusions

Product Name: Adzynma	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

AND

2 - Trial and inadequate response, contraindication or intolerance to plasma-based infusions [B, 11]

2 . Revision History

Date	Notes
2/23/2024	New program

Prior Authorization Guideline

Guideline ID	GL-99426
Guideline Name	Aemcolo
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Aemcolo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of travelers' diarrhea

AND

2 - History of failure, contraindication, or intolerance to ONE of the following:

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99709
Guideline Name	Afinitor
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Neuroendocrine tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Neuroendocrine tumors of pancreatic origin
- Neuroendocrine tumors of gastrointestinal origin
- Neuroendocrine tumors of lung origin

- Neuroendocrine tumors of thymic origin

AND

2 - Disease is progressive

AND

3 - One of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal cell cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell cancer

AND

2 - One of the following:

2.1 Disease has relapsed

OR

2.2 BOTH of the following

- Medically or surgically unresectable tumor
- Diagnosis of Stage IV disease

AND

3 - One of the following:

3.1 Patient with non-clear cell histology

OR

3.2 Both of the following:

3.2.1 Patient with predominantly clear cell histology

AND

3.2.2 History of failure, contraindication, or intolerance to at least one prior systemic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib), Opdivo (nivolumab), Cabometyx (cabozantinib)]

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal cell cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is not a candidate for curative surgical resection

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Waldenströms macroglobulinemia
- Lymphoplasmacytic lymphoma

AND

2 - One of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Disease is recurrent

OR

2.2 Disease is metastatic

AND

3 - One of the following:

3.1 Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]

OR

3.2 BOTH of the following:

- Disease is hormone receptor negative (HR-)
- Disease has clinical characteristics that predict a HR+ tumor

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - One of the following:

5.1 Patient is a postmenopausal woman

OR

5.2 BOTH of the following:

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

OR

5.3 Patient is male

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Used in combination with Aromasin (exemestane)

AND

6.1.2 One of the following:

6.1.2.1 Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy

OR

6.1.2.2 Patient was treated with tamoxifen at any time

OR

6.2 Used in combination with ONE of the following:

- Fulvestrant

- Tamoxifen

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of classical Hodgkin lymphoma

AND

2 - ONE of the following:

- Disease is refractory
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Hodgkin Lymphoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PEComa (perivascular epitheliod cell tumor)

OR

2 - Diagnosis of recurrent angiomyolipoma

OR

3 - Diagnosis of lymphangioleiomyomatosis

OR

4 - All of the following:

4.1 Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

4.2 Disease has progressed after single agent therapy with ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

AND

4.3 Used in combination with ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least one prior first-line chemotherapy regimen

OR

2.2 Patient has extrathoracic metastatic disease

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is recurrent or progressive

AND

3 - Surgery and/or radiation is not possible

AND

4 - Used in combination with bevacizumab (e.g., Avastin, Myasi)

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with letrozole

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis complex associated partial-onset seizures

AND

2 - Used as adjunctive therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Afinitor therapy

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99427
Guideline Name	Afrezza
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Afrezza	
Diagnosis	Type 1 or Type 2 diabetes mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Forced Expiratory Volume (FEV1) within the last 60 days is greater than or equal to 70% of expected normal as determined by the physician

AND

4 - Afrezza will not be approved in patients with ONE of the following:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months)
- With chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease)

Product Name: Afrezza	
Diagnosis	Type 1 or Type 2 diabetes mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in Forced Expiratory Volume (FEV1)

AND

2 - Patient continues to be unable to self-inject short-acting insulin due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Patient continues to not smoke cigarettes

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

Guideline ID	GL-144824
Guideline Name	Agamree (vamorolone)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Agamree	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has received genetic testing for a mutation of the dystrophin gene

AND

4 - Submission of medical records (e.g., chart notes) documenting one of the following:

4.1 Patient has a confirmed mutation of the dystrophin gene

OR

4.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

5 - Submission of medical records (e.g., chart notes) or paid claims confirming patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend

AND

6 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

7 - One of the following:

7.1 For patients less than or equal to 50kg, dose will not exceed 6mg/kg of body weight once daily

OR

7.2 For patients greater than 50kg, dose will not exceed 300mg/day

Product Name: Agamree	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting patient has experienced a benefit from therapy (e.g., improvement in preservation of muscle strength)

AND

2 - One of the following:

2.1 For patients less than or equal to 50kg, dose will not exceed 6mg/kg of body weight once daily

OR

2.2 For patients greater than 50kg, dose will not exceed 300mg/day

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend

2 . Revision History

Date	Notes
3/25/2024	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-133833
Guideline Name	Airsupra (albuterol-budesonide)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Airsupra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - Patient is 18 years of age or older

AND

3 - Trial and failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Brand Symbicort

AND

4 - Trial, failure, contraindication or intolerance to BOTH of the following:

- Generic albuterol inhaler
- A preferred inhaled corticosteroid (e.g, Pulmicort, Brand Flovent, Asmanex)

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with Airsupra instead of taking individual products in combination (i.e., albuterol inhaler and Pulmicort)

Product Name: Airsupra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

2 . Revision History

Date	Notes

9/28/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99428
Guideline Name	Aldurazyme - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Aldurazyme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Both the following:

1.2.1 Confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I)

AND

1.2.2 Have moderate to severe symptoms

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

Guideline ID	GL-99674
Guideline Name	Alecensa
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Metastatic
- Recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name: Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Product Name: Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Alecensa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Alecensa	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alecensa therapy

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-99429
Guideline Name	Alinia
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Giardia lamblia
Approval Length	3 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giardiasis

AND

2 - History of failure, contraindication, or intolerance to metronidazole

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Cryptosporidium parvum
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cryptosporidiosis

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

Guideline ID	GL-105169
Guideline Name	Alpha Interferons - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Intron A	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hairy cell leukemia

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of condylomata acuminata (genital or perianal)

OR

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of AIDS-related Kaposi's sarcoma

OR

4 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of leptomeningeal metastases

OR

5 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of meningiomas

OR

6 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of kidney cancer

OR

7 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting treatment of myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or primary myelofibrosis (PM)

OR

8 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of follicular lymphoma

OR

9 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of adult T-cell leukemia, lymphoma

OR

10 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of mycosis fungoides, Sézary syndrome

OR

11 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of desmoid tumors/aggressive fibromatosis

OR

12 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of giant cell tumor of the bone

OR

13 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of malignant melanoma

Product Name: Alferon N	
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting

treatment of refractory or recurring external condylomata acuminata (genital or venereal warts) due to the human papillomavirus (HPV) infection

2 . Revision History

Date	Notes
3/24/2022	Removed Sylatron from guideline, Added Submission of Medical Records

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Prior Authorization Guideline

Guideline ID	GL-138189
Guideline Name	Alpha-1 Proteinase Inhibitors
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, Zemaira	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has clinically evident emphysema

AND

2 - Submission of medical records (e.g., chart notes) documenting a diagnosis of severe congenital deficiency of Alpha1- proteinase inhibitor (alpha1 antitrypsin deficiency)

AND

3 - For Glassia requests ONLY: Paid claims or submission of medical records (e.g., chart notes) (document drug, duration, and date of use) confirming trial and failure, contraindication or intolerance to ALL of the following:

- Aralast NP
- Prolastin-C or Prolastin-C liquid
- Zemaira

2 . Revision History

Date	Notes
1/23/2024	Added Glassia (NP), Prolastin-C, and Zemaira as targets.

Prior Authorization Guideline

Guideline ID	GL-109871
Guideline Name	Alzheimer's Agents - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/27/2022

1 . Criteria

Product Name: Brand Aricept, generic donepezil, Brand Namenda/Namenda XR, generic memantine/memantine XR, Brand Razadyne, generic galantamine hydrobromide, Brand Razadyne ER, generic galantamine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of dementia of the Alzheimer’s type	

Product Name: Brand Exelon, generic rivastigmine	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dementia of the Alzheimer's type

OR

2 - Diagnosis of dementia associated with Parkinson's disease

Product Name: Adlarity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dementia of the Alzheimer's type

AND

2 - One of the following:

2.1 History of failure, contraindication or intolerance to ALL of the following preferred drugs* (verified via paid pharmacy claims):

- generic donepezil
- generic galantamine IR/ER
- generic memantine
- generic oral rivastigmine

OR

2.2 Both of the following:

2.2.1 History of failure, contraindication or intolerance to generic rivastigmine patch* (verified via paid pharmacy claims)

AND **2.2.2** Patient is unable to swallow oral formulations or has documented swallowing difficulties	
Notes	*PA may be required

2 . Revision History

Date	Notes
7/27/2022	Added XR formulations of Namenda/memantine to product name section. No change to criteria.

Prior Authorization Guideline

Guideline ID	GL-114478
Guideline Name	Amvuttra (vutrisiran)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Amvuttra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M)

AND

3 - Two of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130
- Patient has a baseline Karnofsky Performance Status score greater than or equal to 60%

AND

4 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, walking ability, quality of life)

AND

5 - Patient has not had a liver transplant

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Amvuttra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to

therapy as evidenced by an improvement in clinical signs and symptoms from baseline (e.g., neuropathy, quality of life, gait speed, nutritional status, decrease in serum TTR level)

AND

2 - Two of the following:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130
- Patient continues to have a Karnofsky Performance Status score greater than or equal to 60%

2 . Revision History

Date	Notes
9/26/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-99431
Guideline Name	Anthelmintics - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Albenza, generic albendazole	
Diagnosis	See Note section*
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Enterobius vermicularis (pinworm)

OR

2 - Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]

OR

3 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

OR

4 - Diagnosis of Ascariasis (Roundworm)

OR

5 - Diagnosis of Mansonella perstans (Filariasis)

OR

6 - Diagnosis of Toxocariasis (Roundworm)

OR

7 - Diagnosis of Trichinellosis

OR

8 - Diagnosis of Trichuriasis (Whipworm)

OR

9 - Diagnosis of Capillariasis

Notes	* Enterobius vermicularis (pinworm), Hydatid Disease [Echinococcosis (Tapeworm)] Ancylostoma/Necatoriasis (Hookworm), Ascariasis (Roundworm), Mansonella perstans (Filariasis), Toxocariasis (Roundworm), Trichinellosis, Trichuriasis (Whipworm), Capillariasis

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Neurocysticercosis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurocysticercosis

Product Name: Brand Stromectol, generic ivermectin	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of intestinal strongyloidiasis due to the nematode parasite Strongyloides stercoralis

OR

2 - Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137595
Guideline Name	Anticonvulsants - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD) • Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: PREFERRED: generic lacosamide, Xcopri; NON-PREFERRED: Aptiom, Briviact, Brand Vimpat	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies)*: (APPLIES TO APTIOM, BRIVIACT, AND BRAND VIMPAT ONLY)

- Carbamazepine
- Divalproex
- Gabapentin
- Fycompa
- generic lacosamide
- Lamotrigine
- Levetiracetam
- Oxcarbazepine
- Phenytoin
- Pregabalin
- Topiramate
- Valproic acid
- Xcopri
- Zonisamide

AND

1.1.3 One of the following: (APPLIES TO APTIOM, BRIVIACT, AND BRAND VIMPAT ONLY)

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 Both of the following:

- Documentation of failure of preferred formulary alternatives due to intolerable side effects
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

AND

1.1.4 Trial and failure, contraindication, or intolerance to generic lacosamide (APPLIES TO BRAND VIMPAT ONLY)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Preferred Drugs may require PA

Product Name: Motpoly XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Patient weighs at least 50 kg

OR

1.2 For continuation of prior therapy for a seizure disorder

Product Name: Fycompa	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Diagnosis of partial-onset or primary generalized tonic-clonic seizures

OR

1.2 For continuation of prior therapy for a seizure disorder

Product Name: Epidiolex	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome

OR

1.2 Diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

1.3 Diagnosis of seizures associated with tuberous sclerosis complex (TSC)

OR

1.4 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Diacomit	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Dravet syndrome and currently taking clobazam

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Fintepla	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome

AND

1.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies)*:

- Divalproex (e.g., generic Depakote)
- Epidiolex

- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives

AND

1.3.1.2 Lack of compliance as a reason for treatment failure has been ruled out

OR

1.3.2 BOTH of the following:

1.3.2.1 Documentation of failure of preferred formulary alternatives due to intolerable side effects

AND

1.3.2.2 Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2.2 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies)*:

- Banzel (rufinamide)
- Clobazam
- Divalproex
- Epidiolex
- Felbamate
- Lamotrigine
- Topiramate
- Valproic Acid

AND

2.3 ONE of the following:

2.3.1 BOTH of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial of preferred formulary alternatives
- Lack of compliance as a reason for treatment failure has been ruled out

OR

2.3.2 BOTH of the following:

- Documentation of failure of preferred formulary alternatives due to intolerable side effects
- Lack of compliance as a reason for treatment failure has been ruled out

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: PREFERRED: Brand Banzel tablets and suspension, generic rufinamide tablets; NON-PREFERRED: generic rufinamide solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

1.1.2 Trial and failure, contraindication, or intolerance to Brand Banzel suspension (APPLIES TO GENERIC RUFINAMIDE SUSPENSION ONLY)

OR

1.2 For continuation of prior therapy for a seizure disorder

Product Name: PREFERRED: generic clobazam; NON-PREFERRED: Brand Onfi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following:

1.1 Both of the following:

- Diagnosis of seizures associated with Lennox-Gastaut syndrome

- Trial and failure, contraindication, or intolerance to generic clobazam (APPLIES TO BRAND ONFI ONLY)

OR

1.2 All of the following:

- Diagnosis of Dravet syndrome
- Patient is currently taking Diacomit
- Trial and failure, contraindication, or intolerance to generic clobazam (APPLIES TO BRAND ONFI ONLY)

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Sympazan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.1.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
- Not used as primary treatment

AND

1.1.3 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies)*:

- Brand Banzel suspension/tablets or runfinamide tablets
- Divalproex
- Felbamate
- Lamotrigine
- Topiramate
- Valproic acid

AND

1.1.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.2 ALL of the following:

1.2.1 Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

AND

1.2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
- Not used as primary treatment

AND

1.2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies)*:

- Carbamazepine
- Divalproex

- Fycompa
- Gabapentin
- Lacosamide
- Lamotrigine
- Levetiracetam
- Oxcarbazepine
- Phenytoin
- Pregabalin
- Topiramate
- Valproic acid
- Xcopri
- Zonisamide

AND

1.2.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.3 ALL of the following:

1.3.1 Diagnosis of Dravet syndrome

AND

1.3.2 Patient is currently taking Diacomit

AND

1.3.3 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.4 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: PREFERRED: generic tiagabine; NON-PREFERRED: Brand Gabitril	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 Trial and failure, contraindication, or intolerance to generic tiagabine (APPLIES TO BRAND GABITRIL ONLY)

OR

1.2 For continuation of prior therapy for a seizure disorder

Product Name: Brand Sabril Oral Solution, generic vigabatrin oral solution, generic vigadrone oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of infantile spasms

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies)*:

- Carbamazepine
- Divalproex
- Fycompa
- Gabapentin
- Lacosamide
- Lamotrigine
- Levetiracetam
- Oxcarbazepine
- Phenytoin
- Pregabalin
- Topiramate
- Valproic acid

- Xcopri
- Zonisamide

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril Tablets, generic vigabatrin tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of complex partial seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies)*:

- Carbamazepine

- Divalproex
- Fycompa
- Gabapentin
- Lacosamide
- Lamotrigine
- Levetiracetam
- Oxcarbazepine
- Phenytoin
- Pregabalin
- Topiramate
- Valproic acid
- Xcopri
- Zonisamide

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: PREFERRED: Brand Trokendi XR; NON-PREFERRED: generic topiramate ER, Brand Qudexy XR, generic topiramate ER sprinkle	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Trial and failure, contraindication, or intolerance to generic topiramate immediate-release (IR) tablet or topiramate IR sprinkle capsule (APPLIES TO GENERIC TOPIRIMATE ER, BRAND QUDEXY XR, AND GENERIC TOPIRIMATE ER SPRINKLE ONLY)

AND

1.1.3 Trial and failure, contraindication, or intolerance to Brand Trokendi XR (APPLIES TO GENERIC TOPIRIMATE ER, BRAND QUDEXY XR, AND GENERIC TOPIRIMATE ER SPRINKLE ONLY)

OR

1.2 For continuation of prior therapy for a seizure disorder

2 . Revision History

Date	Notes
12/15/2023	Updates from Oct P&T: Updated Preferred and NP drugs and criteria/ prerequisites.

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Prior Authorization Guideline

Guideline ID	GL-135229
Guideline Name	Antidepressants - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: generic citalopram oral solution, generic fluoxetine oral solution, generic sertraline oral conc for solution	
Diagnosis	Requests for Patients greater than 12 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The member is unable to swallow the oral tablet/capsule.	

Product Name: Amitriptyline, amoxapine, bupropion tabs/SR tabs/XL tabs (150 and 300mg), citalopram tabs/oral soln, clomipramine, desipramine, doxepin caps/oral conc for solution, duloxetine capsules (20, 30, 60mg), escitalopram, fluoxetine caps/oral soln, fluvoxamine IR,

generic mirtazapine tabs/ODT, imipramine tabs/caps, nortriptyline caps/oral soln, paroxetine tabs, protriptyline, sertraline tabs/oral soln, trazodone, trimipramine, venlafaxine tabs/ER capsules	
Diagnosis	PREFERRED DRUG Requests for patient 6 years of age or younger
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

Notes	Drug may require PA

Product Name: Brand Anafranil, Aplenzin, Auvelity, Brand Celexa, generic citalopram capsules, Brand Cymbalta, generic duloxetine 40mg caps, Drizalma , Brand Effexor XR, generic venlafaxine ER tabs, Emsam, Fetzima, fluvoxamine ER, Brand Lexapro, maprotiline, Marplan, Brand Nardil, generic phenelzine, nefazodone, Brand Norpramin, Brand Pamelor caps/oral soln, Brand Parnate, generic tranylcypromine, Brand Paxil, generic paroxetine capsules, Brand Paxil susp, generic paroxetine suspension, Brand Paxil CR, generic paroxetine ER, Pexeva, Brand Pristiq, generic desvenlafaxine ER, Brand Prozac, generic fluoxetine tablets, Brand Remeron SLTB, Brand Remeron, Trintellix, Viibryd, Brand Wellbutrin SR, Brand Wellbutrin XL/Forfivo, generic bupropion ER (XL) 450mg tabs, Brand Zoloft, generic sertraline capsules	
Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

AND

3 - Patient has a history of failure, contraindication or intolerance to at least 3 preferred alternatives*

- Bupropion (Generic Wellbutrin)
- Bupropion SR (Generic Wellbutrin SR)
- Bupropion XL (Generic Wellbutrin XL)
- Citalopram (Generic Celexa)
- Duloxetine 20mg, 30mg, or 60 mg capsules
- Escitalopram tablets (Generic Lexapro)
- Esketamine (Spravato)
- Fluoxetine capsules (Generic Prozac)
- Fluoxetine solution (Generic Prozac)
- Fluvoxamine tablets (Generic Luvox)
- Mirtazapine (Generic Remeron)
- Paroxetine tablets (Generic Paxil)
- Sertraline tablets (Generic Zoloft)
- Trazodone (Generic Desyrel)
- Venlafaxine (Generic Effexor)
- Venlafaxine ER capsules (Generic Effexor ER)

Notes	*Drug may require PA

Product Name: Brand Venlafaxine besylate ER	
Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

AND

3 - Patient has history of failure or intolerance to preferred generic venlafaxine or venlafaxine ER

AND

4 - Patient has a history of failure, contraindication or intolerance to at least 2 preferred alternatives*

- Bupropion (Generic Wellbutrin)
- Bupropion SR (Generic Wellbutrin SR)
- Bupropion XL (Generic Wellbutrin XL)
- Citalopram (Generic Celexa)
- Duloxetine 20mg, 30mg, or 60 mg capsules
- Escitalopram tablets (Generic Lexapro)
- Esketamine (Spravato)
- Fluoxetine capsules (Generic Prozac)
- Fluoxetine solution (Generic Prozac)
- Fluvoxamine tablets (Generic Luvox)
- Mirtazapine (Generic Remeron)
- Paroxetine tablets (Generic Paxil)
- Sertraline tablets (Generic Zoloft)
- Trazodone (Generic Desyrel)

Notes	*Drug may require PA

2 . Revision History

Date	Notes
10/25/2023	Product updates: added generic paroxetine susp to NP section. Specify tablet formulation of sertraline is the preferred t/f alt where applicable.

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Prior Authorization Guideline

Guideline ID	GL-99432
Guideline Name	Antiemetics - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Nausea and vomiting associated with cancer chemotherapy
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prevention or treatment of nausea and vomiting associated with cancer chemotherapy	

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Nausea and vomiting associated with radiotherapy
Approval Length	3 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Prevention or treatment of nausea and vomiting associated with radiotherapy (total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen)

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Postoperative nausea and/or vomiting
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Prevention of postoperative nausea and/or vomiting (administration prior to induction of anesthesia)

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

Guideline ID	GL-99587
Guideline Name	Antiglaucoma Agents - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zioptan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of elevated intraocular pressure due to ocular hypertension or open angle glaucoma	

2 . Revision History

Date	Notes

10/25/2021	Removed Azopt, Brand/generic Travatan Z as targets

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Prior Authorization Guideline

Guideline ID	GL-99551
Guideline Name	Antipsoriatic Agents
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Dovonex cream, generic calcipotriene cream, Brand Calcitrene ointment, generic calcipotriene ointment, Brand Vectical, generic calcitriol ointment	
Diagnosis	Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of psoriasis	

AND

2 - History of failure, contraindication, or intolerance to TWO medium to Very high potency corticosteroid topical treatments (see Table 1 in Background section)

2 . Background

Benefit/Coverage/Program Information

Table 1. Relative Potency of Selected Topical Corticosteroid Products

Drug	Dosage Form	Strength
Super High Potency		
Augmented betamethasone dipropionate (Diprolene)	Gel, Ointment	0.05%
Clobetasol propionate (Temovate, Temovate E)	Cream, Solution	0.05%
Halobetasol propionate (Ultravate)	Cream	0.05%
High Potency		
Augmented betamethasone dipropionate (Diprolene, Diprolene AF)	Cream, Lotion	0.05%
Betamethasone dipropionate	Lotion, Ointment	0.05%
Fluocinonide (Lidex, Lidex E)	Cream, Solution	0.05%
Triamcinolone acetonide (Kenalog)	Cream, Ointment	0.5%
Medium Potency		
Betamethasone valerate (Beta-Val)	Cream	0.1%

Fluocinolone acetonide (Synalar)	Cream, Ointment	0.025%
Fluticasone propionate (Cutivate)	Cream, Lotion	0.05%
	Ointment	0.005%
Hydrocortisone butyrate (Locoid)	Ointment, Solution	0.1%
Mometasone furoate (Elocon)	Cream, Ointment, Solution	0.1%
Prednicarbate (Dermatop)	Cream	0.1%
Triamcinolone acetonide (Kenalog)	Cream, Lotion, Ointment	0.1%
	Ointment	0.025%

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Prior Authorization Guideline

Guideline ID	GL-138184
Guideline Name	Antipsychotics - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Brand Abilify tablets, generic aripiprazole tablets, Brand Geodon capsules, generic ziprasidone capsules, Brand Latuda, generic lurasidone, lithium carbonate (capsules, tablets, ER tablets, oral solution), Brand Lithobid, Brand Risperdal (tablets, solution) generic risperidone (tablets, ODT, solution), Brand Seroquel, generic quetiapine, Brand Zyprexa, Brand Zyprexa Zydis, generic olanzapine (tablets, ODT)	
Diagnosis	PA Required for Patients < 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient has been diagnosed per current DSM (Diagnostic and Statistical Manual of Mental Disorders) criteria with one of the following disorders:	

- Bipolar Spectrum Disorder
- Schizophrenic Spectrum Disorder
- Tourette's or other tic disorder
- Autism Spectrum Disorder

AND

2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for antipsychotic medications

AND

3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for antipsychotic medications

AND

4 - The above documentation includes information on the expected outcomes and an evaluation of potential adverse events

AND

5 - The patient does not have a known hypersensitivity to the requested agent

Product Name: chlorpromazine tablets, fluphenazine (tablets, oral concentrate, elixir), haloperidol tablets and oral concentrate, loxapine, molindone, perphenazine, pimozide, thioridazine, thiothixene, trifluoperazine	
Diagnosis	PA Required for Patients < 12 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been diagnosed per current DSM (Diagnostic and Statistical Manual of Mental Disorders) criteria with one of the following disorders:

- Bipolar Spectrum Disorder
- Schizophrenic Spectrum Disorder
- Tourette's or other tic disorder
- Autism Spectrum Disorder

AND

2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for antipsychotic medications

AND

3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for antipsychotic medications

AND

4 - The above documentation includes information on the expected outcomes and an evaluation of potential adverse events

AND

5 - The patient does not have a known hypersensitivity to the requested agent

Product Name: chlorpromazine injection, Brand Clozaril, generic clozapine (tablets, ODT), fluphenazine decanoate, Brand Haldol decanoate injection, generic haloperidol decanoate, Brand Haldol lactate injection, generic haloperidol lactate injection	
Diagnosis	PA Required for Patients < 18 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 The requested medication must be used for an FDA (Food and Drug Administration) approved indication

OR

1.1.1.2 The use of the drug is supported by information in ONE of the following appropriate compendia of literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.2 The patient meets the FDA minimum age limit or the prescriber attests they are aware of FDA labeling regarding the use of the antipsychotic medication and feels the treatment with the requested medication is medically necessary (Document rationale for use)

OR

1.2 The patient is currently on the requested medication

Product Name: Abilify Asimtufii, Abilify Maintena	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with aripiprazole

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Abilify Mycite	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has ONE of the following:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder
- Autism
- Major depressive disorder
- Tourette's

AND

1.1.2 Submission of medical records or claims history documenting the patient is currently prescribed aripiprazole and tolerates the medication

AND

1.1.3 Submission of medical records or claims history documenting the patient's adherence to aripiprazole is less than 80 percent within the past 6 months (medication adherence percentage is defined as the number of pills absent in a given time period divided by the number of pills prescribed during that same time, multiplied by 100)

AND

1.1.4 ALL of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success:

- Utilization of a pill box
- Utilization of a smart phone reminder (ex. alarm, application, or text reminder)
- Involving family members or friends to assist
- Coordinating timing of dose to coincide with dosing of another daily medication

AND

1.1.5 Submission of medical records or claims history documenting patient has experienced life-threatening or potentially life-threatening symptoms, or has experienced a severe worsening of symptoms leading to a hospitalization which was attributed to the lack of adherence to aripiprazole

AND

1.1.6 Prescriber acknowledges that Abilify MyCite has not been shown to improve patient adherence and attests that Abilify MyCite is medically necessary for the patient to maintain compliance, avoid life-threatening worsening of symptoms, and reduce healthcare resources utilized due to lack of adherence

AND

1.1.7 Prescriber agrees to track and document adherence of Abilify MyCite through software provided by the manufacturer

AND

1.1.8 The patient has a history of failure, contraindication, or intolerance or reason or special circumstance they cannot use TWO of the following: (Drug may require PA)

- Abilify Maintena
- Invega Sustenna
- Risperdal Consta
- Aristada
- Perseris

OR

1.2 ONE of the following:

1.2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

1.2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Product Name: Abilify Mycite

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient is clinically stable on Abilify MyCite

AND

2 - Submission of medical records or claims history documenting that the use of Abilify MyCite has increased adherence to 80 percent or more

AND

3 - Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent

Product Name: Aristada, Aristada Initio	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral aripiprazole

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Invega Sustenna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral paliperidone or oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Invega Trinza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - Patient has been treated with Invega Sustenna for at least 4 months

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Invega Hafyera	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - Patient has been treated with Invega Sustenna or Invega Trinza for at least 6 months

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Lybalvi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of schizophrenia

AND

1.1.2 Both of the following:

1.1.2.1 Patient has a history of failure, contraindication or intolerance to at least FOUR of the following:

- Aripiprazole oral (generic Abilify)
- Aripiprazole injectable formulations (Abilify Maintena, Aristada, Aristada Initio)
- Clozapine/clozapine ODT
- Lurasidone
- Paliperidone oral
- Paliperidone injectable formulations (e.g., Invega Trinza, Invega Sustenna, Invega Hafyera)
- Quetiapine
- Risperidone/risperidone ODT
- Risperidone injectable formulations (Perseris, Risperdal Consta)

AND

1.1.2.2 Failure to respond to generic olanzapine (Generic Zyprexa) given at maximum dosage

OR

1.2 All of the following:

1.2.1 Diagnosis of bipolar I disorder

AND

1.2.2 History of failure, contraindication or intolerance to ALL of the following preferred alternatives:

- Lamotrigine
- Lithium
- Valproate

AND

1.2.3 History of failure, contraindication or intolerance to THREE of the following preferred alternatives:

- Aripiprazole
- Lurasidone
- Quetiapine
- Risperidone

OR

1.3 One of the following:

1.3.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

1.3.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Perseris	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Risperdal Consta

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Rykindo, generic risperidone ER IM	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - History of failure, contraindication or intolerance to Risperdal Consta

AND

4 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Uzedy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - History of failure, contraindication or intolerance to BOTH of the following:

- Perseris
- Risperdal Consta

AND

4 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Brand Abilify tablets, Adasuve, generic aripiprazole (ODT, solution), chlorpromazine tablets, Brand Clozaril, Fanapt, fluphenazine (injection, tablets), Brand Geodon (capsules, injection) generic ziprasidone (capsules, injection), Brand Haldol decanoate injection, generic haloperidol injection, Brand Invega tablets, generic paliperidone ER tablets, Brand Latuda, Brand Lithobid, loxapine, perphenazine-amitriptyline, prochlorperazine injection, Brand Risperdal (tablets, solution), generic risperidone solution, Brand Saphris, generic asenapine sublingual tablets, Secuado, Brand Seroquel, Brand Seroquel XR, generic quetiapine ER tablets, Brand Symbyax, generic fluoxetine-olanzapine, Versacloz, Brand Zyprexa (tablets, injection), Zyprexa Relprevv, Brand Zyprexa Zydis

Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 ONE of the following:

1.1.1.1 Patient has a history of failure, contraindication or intolerance to at least FOUR of the following:

- Aripiprazole oral (generic Abilify)
- Aripiprazole injectable formulations (Abilify Maintena, Aristada, Aristada Initio)
- Clozapine/clozapine ODT
- Lurasidone
- Olanzapine/olanzapine ODT
- Paliperidone oral** (DOES NOT APPLY TO REQUESTS FOR PALIPERIDONE ER TABLETS)
- Paliperidone injectable formulations (Invega Sustenna, Invega Trinza, Hafyera)
- Quetiapine
- Risperidone/risperidone ODT
- Risperidone injectable formulations (Perseris, Risperdal Consta)

OR

1.1.1.2 There are no preferred formulary alternatives for the requested drug

AND

1.1.2 If the request is for a multi-source brand medication (i.e., MSC O), ONE of the following:

1.1.2.1 BOTH of the following:

- The brand is being requested because of an adverse reaction, allergy or sensitivity to the generic and the prescriber must attest to submitting the FDA MedWatch Form for allergic reactions to the medications

- If there are generic product(s), the member has tried at least three (if available)

OR

1.1.2.2 ONE of the following:

- The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure)
- The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)
- Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.1.3 ONE of the following:

1.1.3.1 The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

1.1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.4 ONE of the following:

1.1.4.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

1.1.4.2 The drug falls within dosing guidelines found in ONE of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.5 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program*

OR

1.2 The requested medication is a behavioral health medication and ONE of the following:

1.2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

1.2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED. **If the request is for generic paliperidone ER tablets, please omit "pal iperidone oral" as an alternative**

2 . Revision History

Date	Notes
12/22/2023	Added generic Risperdal Consta as NP target (mirrors Rykindo)

Prior Authorization Guideline

Guideline ID	GL-126970
Guideline Name	Anxiolytics - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/23/2023

1 . Criteria

Product Name: buspirone, Brand Xanax tabs, generic alprazolam tabs, alprazolam ODT, alprazolam conc, Brand Xanax XR, generic alprazolam ER, chlordiazepoxide, Brand Tranxene T, generic clorazepate dipotassium, Brand Valium tabs, generic diazepam tabs, diazepam conc, diazepam oral soln, Brand Ativan, Loreev XR, generic lorazepam, lorazepam conc, generic oxazepam, Brand Klonopin tabs, generic clonazepam tabs, clonazepam ODT	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted).	

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

Product Name: Loreev XR	
Diagnosis	Requests for Patients 6 years of age and older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure, or contraindication to generic lorazepam

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

Product Name: buspirone, Brand Xanax tabs, generic alprazolam tabs, alprazolam ODT, alprazolam conc, Brand Xanax XR, generic alprazolam ER, chlordiazepoxide, Brand Tranxene T, generic clorazepate dipotassium, Brand Valium tabs, generic diazepam tabs, diazepam conc, diazepam oral soln, Brand Ativan, Loreev XR, generic lorazepam, lorazepam conc, generic oxazepam, Brand Klonopin tabs, generic clonazepam tabs, clonazepam ODT	
Diagnosis	Reject 75: Drug Utilization Review: Greater than 1 Anxiolytic in 30 days
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The medication is being used to adjust the dose of the drug

OR

2 - The medication will be used in place of the previously prescribed drug, and not in addition to it

OR

3 - The medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

4 - The physician attests they are aware of the multiple anxiolytics prescribed to the patient and feels treatment with both medications is medically necessary (Document rationale for use)

2 . Revision History

Date	Notes
6/22/2023	Updated DUR Reject code from 88 to rej 75. No changes to clinical c riteria.

Prior Authorization Guideline

Guideline ID	GL-99571
Guideline Name	Apidra and Apidra Solostar
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Apidra and Apidra Solostar	
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for Apidra, and Apidra Solostar should be denied. The plan's preferred products are.

- Generic Novolog
- Generic Humalog
- Novolog
- Humalog

2 . Revision History

Date	Notes
7/13/2021	New policy

Prior Authorization Guideline

Guideline ID	GL-107440
Guideline Name	Apomorphine products (Apokyn, Kynmobi)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Brand Apokyn, generic apomorphine injection, Kynmobi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of Parkinson's disease

AND

1.2 Medication will be used as intermittent treatment for OFF episodes

AND

1.3 Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

1.4 Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

1.5 History of failure, contraindication, or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

AND

2 - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

Product Name: Brand Apokyn, generic apomorphine injection, Kynmobi	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
5/24/2022	Added generic apomorphine injection and Kynmobi as targets

Prior Authorization Guideline

Guideline ID	GL-99514
Guideline Name	Aquadeks
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Aquadeks	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis	

2 . Revision History

Date	Notes
4/10/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-105172
Guideline Name	Arcalyst
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) [including Familial Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), etc]

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Arcalyst therapy

2 . Revision History

Date	Notes
3/24/2022	Updated diagnosis verbiage for clarification. Added Submission of M edical Records.

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Prior Authorization Guideline

Guideline ID	GL-99710
Guideline Name	Arikayce
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting respiratory cultures positive for MAC within the previous 6 months

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting the patient has been receiving a multidrug background regimen containing at least TWO of the following agents for a minimum of 6 consecutive months within the past 12 months (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

- Macrolide antibiotic* (e.g., azithromycin, clarithromycin)
- Ethambutol*
- Rifamycin antibiotic* (e.g., rifampin, rifabutin)

AND

4 - Patient will continue to receive a multidrug background regimen

AND

5 - Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

AND

6 - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 micrograms per milliliter (mcg/mL)

AND

7 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	*Drug may require PA)

Product Name: Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation that the patient has achieved negative respiratory cultures

OR

1.2 ALL of the following:

1.2.1 Patient has not achieved negative respiratory cultures while on Arikayce

AND

1.2.2 Physician attestation that patient has demonstrated clinical benefit while on Arikayce

AND

1.2.3 In vitro susceptibility testing of most recent (within 6 months) positive culture with available susceptibility testing documents that the Mycobacterium avium complex (MAC) isolate is susceptible to amikacin with an minimum inhibitory concentration (MIC) of less than 64 micrograms per milliliter (mcg/mL)

AND

1.2.4 Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting that the patient continues to receive a multidrug background regimen containing at least TWO of the following agents (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

- Macrolide antibiotic* (e.g., azithromycin, clarithromycin)
- Ethambutol*
- Rifamycin antibiotic* (e.g., rifampin, rifabutin)

AND

3 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	*Drug may require PA

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-125916
Guideline Name	Atorvaliq (atorvastatin oral suspension)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/20/2023

1 . Criteria

Product Name: Atorvaliq	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is less than 10 years of age

AND

1.1.2 Prescribed by or in consultation with a cardiologist

OR

1.2 Both of the following:

1.2.1 Medication is being used for one of the following:

1.2.1.1 To reduce the risk of one of the following:

- Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
- MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD
- Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD

OR

1.2.1.2 As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in one of the following:

- Adults with primary hyperlipidemia
- Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)

OR

1.2.1.3 As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)

OR

1.2.1.4 As an adjunct to diet for the treatment of adults with one of the following:

- Primary dysbetalipoproteinemia
- Hypertriglyceridemia

AND

1.2.2 One of the following:

1.2.2.1 Trial and failure, contraindication, or intolerance to generic atorvastatin tablets (verified via paid pharmacy claims or submitted chart notes)

OR

1.2.2.2 Patient is unable to swallow oral tablets

2 . Revision History

Date	Notes
5/19/2023	Revised verbiage for patients under 10 yo

Prior Authorization Guideline

Guideline ID	GL-137610
Guideline Name	Austedo (deutetrabenazine)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Austedo, Austedo XR	
Diagnosis	Moderate to Severe Tardive dyskinesia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia (TD) secondary to treatment with a centrally acting dopamine receptor blocking agent (DRBA)

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of the AIMS items 1 through 9

AND

5 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

6 - Dose does not exceed 48 mg per day

Product Name: Austedo, Austedo XR	
Diagnosis	Moderate to Severe Tardive dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline score of any one of the AIMS items 1 through 9

AND

2 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

3 - Dose does not exceed 48 mg per day

Product Name: Austedo, Austedo XR	
Diagnosis	Chorea Associated with Huntington Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea associated with Huntington's Disease

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Targeted mutation analysis demonstrates a cytosine-adenine-guanine (CAG) trinucleotide expansion of ≥ 36 repeats in the huntingtin (HTT) gene

AND

5 - Patient has a Unified Huntington Disease Rating Scale (UHDRS) score ranging from 1 to 4 on any one of UHDRS chorea items 1 through 7

AND

6 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

7 - Dose does not exceed 48 mg per day

Product Name: Austedo, Austedo XR	
Diagnosis	Chorea Associated with Huntington Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline score of any one of the UHDRS chorea items 1 through 7

AND

2 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

3 - Dose does not exceed 48 mg per day

2 . Revision History

Date	Notes
12/11/2023	Updates from Oct P&T: removed step through Austedo IR for Austedo XR (now preferred)

Prior Authorization Guideline

Guideline ID	GL-143793
Guideline Name	Azole Antifungals
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Systemic Fungal Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following

1.1 Diagnosis of ONE of the following:

- Blastomycosis
- Histoplasmosis

- Aspergillosis

OR

1.2 Both of the following:

1.2.1 Diagnosis of coccidioidomycosis

AND

1.2.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fingernail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

AND

2 - Patient has a history of at least a 6-week trial resulting in therapeutic failure, contraindication, intolerance, or resistance to Terbinafine as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules

Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Three months have elapsed since completion of initial therapy for fingernail onychomycosis

AND

1.2 Documentation of positive clinical response to therapy

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of toenail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

AND

2 - Patient has a history of at least a 12-week trial resulting in therapeutic failure, contraindication, intolerance, or resistance to Terbinafine as evidenced by submission of medical records or claims history.

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Nine months have elapsed since completion of initial therapy for toenail onychomycosis

AND

1.2 Documentation of positive clinical response to therapy

Product Name: Brand Sporanox Oral Solution, generic itraconazole oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Oropharyngeal candidiasis
- Esophageal candidiasis

Product Name: Brand Vfend tablets, generic voriconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.2 ALL of the following:

- Diagnosis of Candidemia
- Patient is non-neutropenic
- Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.3 Both of the following:

1.3.1 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

AND

1.3.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.4 Diagnosis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.6 Diagnosis of Exserohilum species infection

Product Name: Brand Vfend Powder for Oral Suspension, generic voriconazole powder for oral suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.1.2 ALL of the following:

- Diagnosis of Candidemia
- Patient is non-neutropenic
- Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.1.3 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

OR

1.1.4 Diagnososis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.1.6 Diagnosis of Exserohilum species infection

AND

1.2 Physician has provided rationale for the patient needing to use voriconazole oral suspension instead of voriconazole tablets.

Product Name: Brand Noxafil tablets, generic posaconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

1.2 One of the following conditions:

1.2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

1.2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name: Noxafil Suspension, Noxafil suspension packets	
Diagnosis	Prophylaxis of Aspergillus or Candida Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

1.2 One of the following conditions:

1.2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

1.2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name: Noxafil Suspension	
Diagnosis	Oropharyngeal Candidiasis (OPC)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of oropharyngeal candidiasis (OPC)

AND

1.2 The patient has a history of failure, contraindication, intolerance, or resistance to TWO of the following as evidenced by submission of medical records or claims history:

- Fluconazole* (generic Diflucan)
- Itraconazole* (generic Sporanox)
- Clotrimazole Lozenges*

Notes	*Drug may require PA

Product Name: Cresemba	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of invasive aspergillosis

AND

1.1.2 Patient has a history of failure, contraindication, intolerance, or resistance to voriconazole* (generic Vfend) as evidenced by submission of medical records or claims history

OR

1.2 Diagnosis of invasive mucormycosis

AND

2 - Both of the following:

- Patient is 6 months of age or older
- Patient weighs 16 kg or greater

Notes	*Drug may require PA

Product Name: Tolsura	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of ONE of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

1.2 Patient has a history of failure, contraindication, intolerance, or resistance to itraconazole* capsules (generic Sporanox) as evidenced by submission of medical records or claims history

Notes	*Drug may require PA

Product Name: Brand Sporanox capsules, generic itraconazole capsules, Brand Sporanox oral solution, generic itraconazole oral solution, Brand Vfend tablets, generic voriconazole tablets, Brand Vfend powder for oral suspension, generic voriconazole powder for oral suspension, Brand Noxafil tablets, generic posaconazole tablets, Noxafil oral suspension, Noxafil suspension packets, Cresemba, Tolsura	
Diagnosis	All Other Diagnoses
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND **2** - The medication is being prescribed by or in consultation with an infectious disease specialist	
Notes	*Authorization duration based on provider recommended treatment du rations, not to exceed 12 months

2 . Revision History

Date	Notes
3/1/2024	Removed Likmez from PA, created new drug-specific guideline.

Prior Authorization Guideline

Guideline ID	GL-99516
Guideline Name	Baxdela
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Baxdela	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	10 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

3.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics or antibiotic regimens:

- Amoxicillin**
- A macrolide**
- Doxycycline**
- A fluoroquinolone**
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Notes	*Note: Authorization will be issued for up to 10 days. **Drug may require PA

Product Name: Baxdela	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 One of the following diagnoses:

3.1.1 Both of the following

3.1.1.1 Acute bacterial skin and skin structure infections

AND

3.1.1.2 Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

3.1.2 Both of the following:

3.1.2.1 Empirical treatment of patients with acute bacterial skin and skin structure infections

AND

3.1.2.2 Presence of MRSA infection is likely

AND

3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

3.3 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)**
- A tetracycline**
- Clindamycin**

OR

4 - All of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

4.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics:

- A penicillin**
- A cephalosporin**
- A tetracycline**
- Sulfamethoxazole-trimethoprim (SMZ-TMP)**
- Clindamycin**

Notes	*Note: Authorization will be issued for up to 14 days. **Drug may require PA

Product Name: Baxdela	
Diagnosis	Off-Label Uses*
Guideline Type	Prior Authorization

Approval Criteria **1** - For continuation of therapy upon hospital discharge **OR** **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication	
Notes	*Note: Authorization duration based on provider recommended treatment durations, up to 6 months.

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-117161
Guideline Name	Belbuca, Butrans - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Diagnosis	Cancer/Hospice/End of Life related pain
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for cancer, hospice, or end of life related pain

AND

2 - If the request is for Belbuca or generic Butrans BOTH of the following:

2.1 Prescriber attests the information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

AND

2.2 The patient has a history of failure, contraindication or intolerance to BRAND Butrans

Notes	* If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for brand buprenorphine patches.

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches	
Diagnosis	Cancer/Hospice/End of Life related pain
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for cancer, hospice, or end of life related pain (Document diagnosis and date of diagnosis)

AND

2 - If the request is for Belbuca or generic Butrans ONLY: Prescriber attests the information

provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Diagnosis	Non-cancer pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

1.1 The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

AND

1.2 Treatment goals are defined, including estimated duration of treatment

AND

1.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

1.4 Patient has been screened for substance abuse/opioid dependence

AND

1.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the

prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

1.6 Pain is moderate to severe and expected to persist for an extended period of time

AND

1.7 Pain is chronic

AND

1.8 Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

AND

1.9 Pain management is required around the clock with a long-acting opioid

AND

2 - The patient has a history of failure, contraindication, or intolerance to a trial of tramadol IR (immediate release), unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (Drug may require PA)

AND

3 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following must be met:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin or pregabalin (Lyrica) titrated to a therapeutic dose (document date of trial)

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial)

AND

4 - If the request is for Belbuca or generic Butrans, the patient has a history of failure, contraindication or intolerance to BRAND Butrans

Notes	* If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for brand buprenorphine patches.

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Diagnosis	Non-cancer pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (document rationale)

AND

3 - Prescriber attests to ALL of the following:

3.1 The information provided is true and accurate to the best of their knowledge and they understand that a routine audit may be performed; and medical information necessary to verify the accuracy of the information provided may be requested

AND

3.2 Treatment goals are defined, including estimated duration of treatment

AND

3.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

3.4 Patient has been screened for substance abuse/opioid dependence

AND

3.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

3.6 Pain is moderate to severe and expected to persist for an extended period of time

AND

3.7 Pain is chronic

AND

3.8 Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

AND

3.9 Pain management is required around the clock with a long-acting opioid

AND

4 - If the request is for Belbuca or generic Butrans, the patient has a history of failure, contraindication, or intolerance to BRAND Butrans

Notes	* If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for brand buprenorphine patches.

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Guideline Type	Quantity Limit

Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the FDA (Food and Drug Administration) maximum dose per day, where an FDA maximum dose per day exists	
Notes	*Approval durations: 12 months for cancer pain/hospice/end of life related pain; 6 months for non-cancer pain/non-hospice/non-end of life related pain

2 . Revision History

Date	Notes
11/21/2022	Added pregabalin as prerequisite option for neuropathic/nerve pain

Prior Authorization Guideline

Guideline ID	GL-114489
Guideline Name	Benlysta (belimumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Benlysta IV, Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic lupus erythematosus

AND

2 - Patient is 5 years of age or older

AND

3 - Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]

AND

4 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

5 - Patient does NOT have severe active central nervous system lupus

AND

6 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Product Name: Benlysta IV, Benlysta SQ	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is 5 years of age or older

AND

3 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

4 - Patient does NOT have severe active central nervous system lupus

AND

5 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Product Name: Benlysta IV, Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus, Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND

2 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

2 . Revision History

Date	Notes
9/26/2022	Updated age requirement. Added IV formulation as target.

Prior Authorization Guideline

Guideline ID	GL-99434
Guideline Name	Benznidazole
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Benznidazole	
Diagnosis	Chagas disease (American trypanosomiasis)
Approval Length	60 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Chagas disease (American trypanosomiasis) due to Trypanosoma cruzi	

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy guidelines starting with B and C from C&S Arizona to Ariz ona Medicaid

Prior Authorization Guideline

Guideline ID	GL-139342
Guideline Name	Bimzelx (bimekizumab-bkzx)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Bimzelx	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g, chart notes) confirming diagnosis of moderate to severe plaque psoriasis

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following:

- At least 3% body surface area (BSA) involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Both of the following (verified via submission of records or paid pharmacy claims):

5.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Enbrel (etanercept)
- Humira (adalimumab)

AND

5.2 Trial and failure, contraindication, or intolerance to Otezla (apremilast)

AND

6 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine)

Product Name: Bimzelx	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming positive clinical response to therapy as evidenced by ONE of the following:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine)

2 . Revision History

Date	Notes
1/23/2024	New program

Prior Authorization Guideline

Guideline ID	GL-99566
Guideline Name	Blood Glucose Monitors
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Non-preferred Blood Glucose Monitors*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is visually impaired	
Notes	*Please reference background table for list of Non-preferred Blood Glucose Monitors **Approve Glucose Monitor at NDC Level

2 . Background

Benefit/Coverage/Program Information

Non-preferred Blood Glucose Monitors*

CONTOUR KIT NEXT LNK	EASY TOUCH KIT MONITOR	EASYMAX V KIT SYSTEM
CONTOUR NXT KIT LINK 2.4	KROGER BGM KIT SYSTEM	EASYMAX NG KIT SYSTEM
CONTOUR KIT NEXT EZ	ELEMENT AUTO KIT SYSTEM	MEIJER BGM KIT ESSENTIA
CONTOUR KIT NEXT	SMARTEST KIT EJECT	MEIJER GLUCO KIT MONITOR
CONTOUR KIT MONITOR	SMARTEST KIT PROTEGE	MEIJER BGM KIT PREMIUM
RELION MICRO KIT	SMARTEST KIT PRONTO	FORA V30A KIT
RELION KIT MONITOR	SMARTEST KIT PERSONA	FORA TN'G KIT VOICE
BD LOGIC KIT MONITOR	GLUCOCOM KIT MONITOR	REFUAH PLUS KIT SYSTEM
BD LATITUDE KIT	RIGHTEST SYS KIT GM300	KROGER BGM KIT
BD LATITUDE KIT SYSTEM	RIGHTEST SYS KIT GM100	KROGER BGM KIT PREMIUM
QUICKTEK KIT	RIGHTEST SYS KIT GM550	CONTOUR KIT LINK 2.4
ADVANCE KIT INTUITIO	IGLUCOSE KIT	EASYMAX V KIT SYSTEM
GLUCOCARD KIT SHNE CON	NOVA MAX KIT SYSTEM	EASYMAX NG KIT SYSTEM
GLUCOCARD KIT SHNE EXP	WAVESENSE KIT KEYNOTE	MYGLUCOHEALT KIT SYSTEM
GLUCOCARD KIT EXPRESSI	AGAMA JAZZ KIT WRLSS 2	MICRODOT KIT SYSTEM
POCKETCHEM KIT EZ	AGAMATRIX KIT PRESTO	ONE TOUCH KIT VERIO FL

GLUCOCARD 01 KIT SYSTEM	WAVESENSE KIT AMP	RELION TRUE KIT MET AIR
GLUCOCARD 01 KIT MINI	SOLUS V2 KIT SYSTEM	VERASENS KIT
GLUCOCARD KIT X-METER	COOL MONITOR KIT	INFINITY KIT VOICE
GLUCOCARD KIT VITAL	TRUERESULT KIT MONITOR	OPTIUM KIT BL GLUC
RELION PREMI KIT COMP SYS	TRUERESULT KIT SYSTEM	PRECISION KIT XTRA
SMART SENSE KIT GLUC SYS	MEIJER BGM KIT ESSENTIA	PRECISION KIT LINK
CVS GLUCOSE KIT METER	MEIJER GLUCO KIT MONITOR	BIOTEL CARE KIT SYSTEM
INFINITY KIT SYSTEM	MEIJER BGM KIT PREMIUM	BIOTEL CARE KIT
EASYPRO KIT MONITOR	FORA V30A KIT	FREESTYLE KIT SIDEKICK
EASYPRO PLUS KIT	FORA TN'G KIT VOICE	FREESTYLE KIT FREEDOM
PRODIGY PCKT KIT METER	REFUAH PLUS KIT SYSTEM	KROGER BGM KIT PREMIUM
PRODIGY AUTO KIT MONITOR	KROGER BGM KIT	CONTOUR KIT LINK 2.4
PRODIGY VOIC KIT METER		
PRODIGY KIT NO CODIN		

3 . Revision History

Date	Notes
7/12/2021	New Program

Prior Authorization Guideline

Guideline ID	GL-99436
Guideline Name	Bonjesta and Diclegis
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Bonjesta, Brand Diclegis, generic doxylamine/pyridoxine	
Diagnosis	Nausea and vomiting associated with pregnancy
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nausea and vomiting associated with pregnancy

AND

2 - Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)

AND

3 - Documented trial and failure or contraindication to a five day trial of over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly)

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy guidelines starting with B and C from C&S Arizona to Ariz ona Medicaid

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Prior Authorization Guideline

Guideline ID	GL-99590
Guideline Name	Brand Over Generic Not Covered
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Generic products on a brand* over generic program	
Guideline Type	Administrative
Approval Criteria **1** - Requests for a generic product on a brand over generic program (presence of Brand over generic-Not Covered clinical program in formulary lookup) shall be denied. The plan's preferred product is the brand medication.	
Notes	* Brand product may require prior authorization.

2 . Revision History

Date	Notes
10/29/2021	Changed effective date to 12/1/21

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Prior Authorization Guideline

Guideline ID	GL-99572
Guideline Name	Brand Vascepa, Generic Icosapent Ethyl, Brand Lovaza, generic omega-3-acid ethyl esters
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Vascepa, Generic Icosapent Ethyl, Brand Lovaza, generic omega-3-acid ethyl esters	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for brand Vascepa, generic Icosapent Ethyl, Brand Lovaza, generic omega-3-acid ethyl esters should be denied. The plan's preferred products are generic over-the-counter omega 3 fatty acids.	

2 . Revision History

Date	Notes
7/14/2021	New Policy

Prior Authorization Guideline

Guideline ID	GL-99541
Guideline Name	Breast Cancer - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Arimidex, generic anastrozole	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Adjuvant treatment of postmenopausal patients with hormone receptor-positive early breast cancer

OR

1.2 First-line treatment of postmenopausal patients with hormone receptor-positive or hormone receptor status unknown locally advanced or metastatic breast cancer

OR

1.3 Postmenopausal patients with disease progression following tamoxifen therapy

Product Name: Brand Aromasin, generic exemestane	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Adjuvant treatment of postmenopausal patients with estrogen receptor-positive early breast cancer who have received 2 to 3 years of tamoxifen and are switched to exemestane for completion of a total of 5 consecutive years of adjuvant hormonal therapy

OR

1.2 Treatment of advanced breast cancer in postmenopausal patients whose disease has progressed following tamoxifen therapy

Product Name: Brand Fareston, generic toremifene	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of metastatic breast cancer in postmenopausal patients with estrogen receptor positive tumors or with tumors of unknown estrogen receptor status

Product Name: Brand Arimidex, generic anastrozole, Brand Aromasin, generic exemestane, Brand Fareston, generic toremifene	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Arimidex, generic anastrozole, Brand Aromasin, generic exemestane, Brand Fareston, generic toremifene	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/3/2021	Arizona Medicaid 7.1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-126227
Guideline Name	Breo Ellipta
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Brand Breo Ellipta, generic fluticasone-vilanterol	
Diagnosis	Asthma, COPD
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of asthma

AND

1.2 Patient is 5 years of age or older

AND

1.3 The patient has a history of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Symbicort

OR

2 - All of the following:

2.1 Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2.2 Patient is 18 years of age or older

AND

2.3 One of the following:

2.3.1 History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza)

OR

2.3.2 History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent/long-acting beta-agonist combination agent (e.g. Anoro Ellipta, Stiolto Respimat)

AND

2.4 The patient has a history of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Symbicort

2 . Revision History

Date	Notes
6/26/2023	Added generic as NP target. Added age requirement criteria.

Prior Authorization Guideline

Guideline ID	GL-120435
Guideline Name	Brexafemme (ibrexafungerp)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Brexafemme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- One intravaginal product (e.g., clotrimazole, miconazole, tioconazole, terconazole, boric acid)
- Oral fluconazole for a minimum of 3 days duration

2 . Revision History

Date	Notes
1/24/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99561
Guideline Name	Brilinta and Effient
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Brilinta, Brand Effient, Generic prasurgrel	
Diagnosis	Acute coronary syndrome (ACS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]

AND

2 - If request is for Effient (prasugrel), patient must be managed with percutaneous coronary intervention (PCI)

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Prior Authorization Guideline

Guideline ID	GL-121788
Guideline Name	Buprenorphine Sublingual Tablet
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Buprenorphine Sublingual Tablet	
Approval Length	6 Months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of opioid abuse/dependence.

AND

2 - One of the following:

2.1 Patient is pregnant or breastfeeding;*

OR

2.2 Both of the following:

2.2.1 Patient had an intolerance or side effect to buprenorphine-naloxone sublingual tablet or film;

AND

2.2.2 Side effects or intolerances to buprenorphine-naloxone sublingual tablet or films were not resolved with a trial of anti-emetics (e.g. ondansetron) or non-opioid analgesics.

OR

2.3 Patient has a contraindication to naloxone.

OR

2.4 Both of the following:

2.4.1 Patient has a severe allergy to naloxone [e.g., Stevens-Johnson syndrome, DRESS (Drug Rash with Eosinophilia and Systemic Symptoms)];

AND

2.4.2 Provider has submitted a copy of the MedWatch Form 3500 to the Food and Drug Administration documenting the adverse reaction

AND

3 - Patient is not currently on ANY of the following:

- Benzodiazepines (e.g. Alprazolam, Diazepam, Lorazepam)
- Hypnotics (e.g. Temazepam, Rozerem, Zolpidem)

• Opioids (e.g. Oxycodone, Tramadol, Hydrocodone) **AND** **4** - Prescriber attests that the Arizona State Board of Pharmacy Controlled Substance Prescription Drug Monitoring Program database has been reviewed and that patient has been warned about the dangers of ingesting concurrent sedating medications	
Notes	*Approve for 1 year if pregnant or breastfeeding

2 . Revision History

Date	Notes
2/27/2023	Removed DATA 2000 criterion

Prior Authorization Guideline

Guideline ID	GL-131952
Guideline Name	Bylvay (odevixibat)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 confirmed by one of the following:

- Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis)

- Genetic Testing

AND

2 - Patient is experiencing both of the following:

- Moderate to severe pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 3 months of age or older

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6 mg

AND

6 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name: Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 Months

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced serum bile acids, improved pruritus)

AND

2 - Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6 mg

Product Name: Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene

AND

2 - Patient is experiencing both of the following:

- Moderate to severe pruritus

- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 12 months of age or older

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name: Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

2 . Revision History

Date	Notes
8/29/2023	Added criteria for new indication Alagille Syndrome

Prior Authorization Guideline

Guideline ID	GL-99601
Guideline Name	Cablivi
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - Cablivi was initiated in the inpatient setting in combination with plasma exchange therapy

AND

3 - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

AND

4 - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) (Documentation of date of prior episode and documentation date of new episode required)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

Guideline ID	GL-131970
Guideline Name	Cabotegravir Containing Agents
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Ca benuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - One of the following:

4.1 Trial and failure, contraindication or intolerance to BOTH of the following:

- Brand Truvada
- Descovy

OR

4.2 Submission of medical records (e.g., chart notes) from provider documenting BOTH of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens

• Patient would be adherent to testing and dosing schedule	
Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude **AND** **2** - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP: • Negative HIV-1 antigen/antibody test • Negative HIV-1 RNA assay	
Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

2 . Revision History

Date	Notes
8/29/2023	Updated t/f criteria verbiage for PrEP indication

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Prior Authorization Guideline

Guideline ID	GL-99531
Guideline Name	Calcium/Vitamin D
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin D deficiency	
Notes	Calcium carbonate and calcium lactate are covered without the need f or prior authorization.

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-114157
Guideline Name	Camzyos (mavacamten)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Camzyos	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain)

AND

3 - Patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose:

- non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
- calcium channel blocker (e.g., verapamil, diltiazem)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved symptom relief)

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50%

AND

3 - Prescribed by or in consultation with a cardiologist

2 . Revision History

Date	Notes
9/20/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-126244
Guideline Name	Caplyta (lumateperone), Rexulti (brexpiprazole), Vraylar (cariprazine)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/7/2023

1 . Criteria

Product Name: Caplyta, Rexulti, Vraylar	
Diagnosis	Schizophrenia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of schizophrenia

AND

2 - One of the following:

2.1 History of failure, contraindication or intolerance to at least FOUR of the following preferred alternatives:

- Aripiprazole oral (generic Abilify)
- Aripiprazole injectable formulations (Abilify Maintena, Aristada, Aristada Initio))
- Clozapine/clozapine ODT
- Lurasidone
- Olanzapine/olanzapine ODT
- Paliperidone oral
- Paliperidone injectable formulations (Invega Sustenna, Invega Trinza, Hafyera)
- Quetiapine
- Risperidone/risperidone ODT
- Risperidone injectable formulations (Perseris, Risperdal Consta)

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Vraylar	
Diagnosis	Bipolar I Disorder
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bipolar I disorder

AND

2 - ONE of the following:

2.1 Both of the following:

2.1.1 History of failure, contraindication or intolerance to ALL of the following preferred alternatives:

- Lamotrigine
- Lithium
- Valproate

AND

2.1.2 History of failure, contraindication or intolerance to THREE of the following preferred alternatives:

- Aripiprazole
- Lurasidone
- Quetiapine
- Risperidone

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with requested medication in the hospital and must continue upon discharge

Product Name: Caplyta, Vraylar	
Diagnosis	Bipolar Depression
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bipolar depression

AND

2 - ONE of the following:

2.1 History of failure, contraindication or intolerance to at least FOUR of the following preferred alternatives:

- Fluoxetine
- Lamotrigine
- Lithium ER
- Lurasidone
- Paroxetine
- Quetiapine
- Valproate
- Combination Therapy (i.e., lithium plus lamotrigine/valproate, lurasidone plus lithium/valproate, olanzapine plus fluoxetine, quetiapine plus lithium/valproate)

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with requested medication in the hospital and must continue upon discharge

Product Name: Rexulti, Vraylar	
Diagnosis	Major Depressive Disorder (MDD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Major depressive disorder (MDD)
- Treatment resistant depression (Applies to Vraylar only)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication or intolerance to at least THREE of the following preferred alternatives:

- Bupropion
- Citalopram
- Duloxetine 20 mg, 30 mg, or 60 mg
- Escitalopram tablets
- Fluoxetine
- Fluvoxamine tablets
- Paroxetine IR tablets
- Sertraline tablets or oral concentrate for solution
- Venlafaxine IR tablets or Venlafaxine ER capsules

AND

2.1.2 History of failure, contraindication or intolerance ALL of the following:

- aripiprazole
- quetiapine ER
- risperidone

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Rexulti	
Diagnosis	Agitation Associated With Dementia Due To Alzheimer's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used for treatment of agitation associated with dementia due to Alzheimer's disease

Product Name: Caplyta	
Diagnosis	Caplyta Requests Exceeding Quantity Limit*
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from one of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols

- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The requested dose falls within dosing guidelines found in one of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

AND **4** - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program **AND** **5** - Physician has provided rationale for needing to exceed the quantity limit of one capsule (42 milligrams [mg]) per day (NOTE: The treatment effect of Caplyta 84mg daily versus placebo was NOT statistically significant in clinical trials.)	
Notes	*Caplyta requests should be reviewed using the above Non-Preferred criteria. This section is for Caplyta quantity limit requests only.

2 . Revision History

Date	Notes
6/6/2023	Added Rexulti as NP target. Updated criteria for most indications

Prior Authorization Guideline

Guideline ID	GL-99678
Guideline Name	Caprelsa
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Caprelsa	
Diagnosis	Medullary thyroid cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medullary thyroid cancer (MTC)

AND

2 - ONE of the following:

- Unresectable locally advanced disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Product Name: Caprelsa	
Diagnosis	Medullary thyroid cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, Papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Follicular carcinoma

- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - One of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

AND

3 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Caprelsa	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, Papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Non-Small Cell Lung Cancer (NSCLC)

AND

2 - Disease is positive for RET gene rearrangement

Product Name: Caprelsa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Caprelsa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Caprelsa therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-104872
Guideline Name	Carbaglu (carglumic acid)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., protein restriction, ammonia scavengers, dialysis)

AND

3 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g. intravenous glucose, insulin, protein restriction, dialysis)

AND

3 - Patient's plasma ammonia level is greater than or equal to 50 micromol/L

AND

4 - Medication will be used for a maximum duration of 7 days

AND

5 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - NAGS deficiency has been confirmed by genetic/mutational analysis

AND

3 - Medication will be used as maintenance therapy

AND

4 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid

Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a positive clinical response to therapy (e.g., plasma ammonia level within the normal range)

2 . Revision History

Date	Notes
3/31/2022	New program for Carbaglu, mirrors ORx LOB. Added submission of MR to each section.

Prior Authorization Guideline

Guideline ID	GL-144825
Guideline Name	Casgevy (exagamglogene autotemcel injection)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Casgevy	
Diagnosis	Sickle Cell Disease
Approval Length	1 Time Authorization in Lifetime*
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of sickle cell disease (SCD)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has genotype βS/βS, βS/β0, or βS/β+

AND

3 - Patient is 12 years of age or older

AND

4 - Provider attests that patient is clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT)

AND

5 - Submission of medical records (e.g., chart notes) documenting patient has a history of at least 4 vaso-occlusive events (VOEs) in the past 24 months as defined by one of the following scenarios:

- Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
- Acute chest syndrome
- Priapism lasting > 2 hours and requiring a visit to a medical facility
- Splenic sequestration

AND

6 - Submission of medical records (e.g., chart notes) confirming patient has obtained a negative test result for all of the following prior to cell collection:

- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human immunodeficiency virus (HIV)

AND

7 - Patient is anticipated to provide an adequate number of cells to meet the minimum recommended dose of 3 x 10^6 CD34+ cells/kg

AND

8 - Patient will receive both of the following:

8.1 Full myeloablative conditioning with busulfan prior to treatment with Casgevy

AND

8.2 Anti-seizure prophylaxis with agents other than phenytoin prior to initiating busulfan conditioning

AND

9 - Prescriber attests that patient will discontinue disease modifying therapies for sickle cell disease (e.g., hydroxyurea, crizanlizumab, voxelotor) 8 weeks before the planned start of mobilization and conditioning

AND

10 - Both of the following:

- Patient has never received any previous sickle cell gene therapy treatment in their lifetime (i.e., Casgevy, Lyfgenia)
- Patient has never received prior allogeneic transplant

AND

11 - Prescribed by a provider at a SCD Treatment center with expertise in gene therapy

AND

12 - Prescribed by one of the following:

- Hematologist/Oncologist

• Specialist with expertise in the diagnosis and management of sickle cell disease	
Notes	*Per prescribing information, Casgevy is for one-time, single dose intr avenous use only

Product Name: Casgevy	
Diagnosis	Transfusion-dependent β-thalassemia (TDT)
Approval Length	1 Time Authorization in Lifetime*
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of transfusion-dependent β-thalassemia (TDT)

AND

2 - Submission of medical records (e.g., chart notes) confirming presence of a mutation at both alleles of the β-globin gene (i.e., β0/β0, β0/β+, β+/β+, β0/βE)

AND

3 - Submission of medical records (e.g., chart notes) confirming ONE of the following:

- Patient has a history of requiring at least 100 mL/kg/year of RBC transfusions in the prior 2 years
- Patient requires 10 units/year of RBC transfusions in the prior 2 years

AND

4 - Patient is 12 years of age or older

AND

5 - Provider attests that patient is clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT)

AND

6 - Submission of medical records (e.g., chart notes) confirming patient has obtained a negative test result for all of the following prior to cell collection:

- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human immunodeficiency virus (HIV)

AND

7 - Patient is anticipated to provide an adequate number of cells to meet the minimum recommended dose of 3 x 10^6 CD34+ cells/kg

AND

8 - Patient does not have any of the following:

- Severely elevated iron in the heart (e.g., patients with cardiac T2* less than 10 msec by MRI)
- Advanced liver disease
- MRI results of the liver demonstrating liver iron content greater than or equal to 15 mg/g (unless biopsy confirms absence of advanced disease)

AND

9 - Both of the following:

- Iron chelation therapy (e.g., deferoxamine, deferasirox) will be discontinued for at least 7 days prior to initiating myeloablative conditioning therapy
- Hydroxyurea, Oxbryta (voxelotor), and Adakveo (crizanlizumab) will be discontinued at least 8 weeks prior to start of mobilization and conditioning

AND

10 - Patient will receive both of the following:

10.1 Full myeloablative conditioning with busulfan prior to treatment with Casgevy

AND

10.2 Anti-seizure prophylaxis with agents other than phenytoin prior to initiating busulfan conditioning

AND

11 - Both of the following:

- Patient has never received any previous transfusion dependent beta-thalassemia gene therapy treatment in their lifetime (i.e., Casgevy, Zynteglo)
- Patient has never received prior allogeneic transplant

AND

12 - Prescribed by a provider at a treatment center with expertise in gene therapy

AND

13 - Prescribed by one of the following:

- Hematologist/Oncologist
- Stem transplant specialist

Notes	*Per prescribing information, Casgevy is for one-time, single dose intr avenous use only

2 . Revision History

Date	Notes
3/25/2024	Added criteria for new indication of beta thalassemia

Prior Authorization Guideline

Guideline ID	GL-99603
Guideline Name	Cayston
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cayston	
Diagnosis	Cystic Fibrosis (CF)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

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Prior Authorization Guideline

Guideline ID	GL-133841
Guideline Name	CGRP Inhibitors - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Ajovy, Emgality 120 mg/ml	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Ajovy, Emgality 120 mg/ml	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

5 - Medication will not be used in combination with another injectable CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

3 - Medication will not be used in combination with another injectable CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Aimovig, Qulipta, Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

AND

4 - Trial and failure, contraindication, or intolerance to ALL of the following:

- Ajovy
- Emgality

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Aimovig, Qulipta, Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines	
Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

AND

4 - Trial and failure, contraindication, or intolerance to ALL of the following:

- Ajovy
- Emgality

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Nurtec ODT, Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month

AND

4 - Patient is 18 years of age or older [I]

AND

5 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to FOUR of the following as evidenced by submission of medical records or claims history:

- naratriptan tablets
- rizatriptan tablets/ODT (Oral Disintegrating Tablets)
- sumatriptan auto injection/cartridge
- Imitrex nasal spray (Brand only)
- zolmitriptan tablets/ODT
- Zomig nasal spray (Brand only)

AND

6 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to Ubrelvy as evidenced by submission of medical records or claims history**

AND

7 - If patient has 4 or more headache days per month, patient must meet one of the following [D]:

7.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

7.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

7.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

AND

8 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

9 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS). **Patients requesting initial aut

	horization who were established on therapy via the receipt of a manuf acturer supplied sample at no cost in the prescriber's office or any for m of assistance from the manufacturer sponsored programs shall be r equired to meet initial authorization criteria as if patient were new to th erapy.

Product Name: Nurtec ODT, Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

3 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Will not be used for preventive treatment of migraine

AND

4 - Patient has fewer than 15 headache days per month

AND

5 - Patient is 18 years of age or older [I]

AND

6 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to TWO of the following as evidenced by submission of medical records or claims history:

- naratriptan tablets
- rizatriptan tablets/ODT (Oral Disintegrating Tablets)
- sumatriptan auto injection/cartridge
- zolmitriptan tablets/ODT
- Zomig nasal spray (Brand only)
- Imitrex nasal spray (Brand only)

AND

7 - If patient has 4 or more headache days per month, patient must meet one of the following [D]:

7.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

7.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

7.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

AND

8 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

9 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - Medication will not be used in combination with another oral CGRP inhibitor

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS).

2 . Revision History

Date	Notes
9/28/2023	Aimovig moved to NP. Removed step through Aimovig for all other N P drugs.

Prior Authorization Guideline

Guideline ID	GL-99700
Guideline Name	Cholbam
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cholbam	
Diagnosis	Bile Acid Synthesis Disorder
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a bile acid synthesis disorder

AND

2 - It is due to single enzyme defects

Product Name: Cholbam	
Diagnosis	Peroxisomal Disorders Including Zellweger Spectrum Disorders
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of peroxisomal disorders including Zellweger spectrum disorders

AND

2 - Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption

AND

3 - It is being used as adjunctive treatment

Product Name: Cholbam	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cholbam therapy

2 . Revision History

Date	Notes
4/10/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-105174
Guideline Name	Cialis for BPH - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Cialis 5mg, generic tadalafil 5mg	
Diagnosis	Benign Prostatic Hyperplasia (BPH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 The patient has a diagnosis of benign prostatic hyperplasia (BPH)

AND

1.2 History of failure, intolerance, or contraindication to BOTH of the following:

- Alpha Blockers (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

AND

1.3 Dose does not exceed 5 milligrams once daily

AND

2 - Provider attests that patient is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas

2 . Revision History

Date	Notes
3/24/2022	Added physician attestation re: patient not using nitrates

Prior Authorization Guideline

Guideline ID	GL-141167
Guideline Name	Cibinqo (abrocitinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/7/2024

1 . Criteria

Product Name: Cibinqo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of moderate to severe atopic dermatitis

AND

2 - Submission of medical records documenting one of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

4 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting ALL of the following**:

4.1 History of failure, contraindication, or intolerance to the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

AND

4.2 Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting trial and failure of a minimum 12-week supply of Dupixent (dupilumab) **

AND

4.3 Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting trial and failure of a minimum 12-week supply of Adbry (tralokinumab-ldrm) **

AND

5 - Not used in combination with biologic immunomodulators (e.g., Dupixent, Adbry) or other immunosuppressants (e.g., azathioprine, cyclosporine)

AND **6** - Patient is 12 years of age or older	
Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication **PA may be required

Product Name: Cibinqo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with biologic immunomodulators (e.g., Dupixent, Adbry) or other immunosuppressants (e.g., azathioprine, cyclosporine)

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)

Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1

Lower-medium potency	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
2/6/2024	Updated criteria to include submission of records where applicable, a dded step through Adbry.

Prior Authorization Guideline

Guideline ID	GL-99712
Guideline Name	Cimzia- Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cimzia	
Diagnosis	Crohn’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderately to severely active Crohn’s disease

AND

1.1.2 History of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to Humira (adalimumab)

AND

1.1.5 Prescribed by or in consultation with a gastroenterologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of Crohn's disease

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Cimzia	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.1.2 History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of moderately to severely active RA

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active psoriatic arthritis

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to THREE of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

1.1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs; e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the

last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.5 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure of a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilsat)

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/19/2021	Arizona Medicaid 7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99518
Guideline Name	CMV and Herpes Virus Agents- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Valcyte tabs/oral soln, generic valganciclovir tabs/oral soln, Brand Cytovene inj, generic ganciclovir inj, Foscavir inj	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Cytomegalovirus (CMV) disease prophylaxis

OR

1.2 Cytomegalovirus (CMV) retinitis

OR

1.3 Cytomegalovirus (CMV) retinitis prophylaxis

OR

1.4 BOTH of the following:

1.4.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.4.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: cidofovir inj	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Cytomegalovirus (CMV) retinitis

OR

1.2 Cytomegalovirus (CMV) retinitis prophylaxis

OR

1.3 BOTH of the following:

1.3.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.3.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: famciclovir tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Herpes genitalis

OR

1.2 Herpes genitalis prophylaxis

OR

1.3 Herpes labialis

OR

1.4 Herpes simplex virus infection

OR

1.5 Herpes zoster (shingles) infection

OR

1.6 BOTH of the following:

1.6.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.6.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and

	are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: Brand Valtrex tabs, generic valacyclovir tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Herpes genitalis

OR

1.2 Herpes genitalis prophylaxis

OR

1.3 Herpes labialis

OR

1.4 Herpes simplex virus infection

OR

1.5 Herpes zoster (shingles) infection

OR

1.6 Varicella (chicken pox) infection

OR

1.7 BOTH of the following

1.7.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.7.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144654
Guideline Name	Colony Stimulating Factors - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: PREFERED: Neupogen, Nivestym	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Leukine, Releuko, Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to BOTH of the following:

- Neupogen
- Nivestym

Product Name: PREFERRED: Neupogen, Nivestym	
Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has completed either induction or consolidation chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Leukine, Releuko, Zarxio

Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has completed either induction or consolidation chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to BOTH of the following:

- Neupogen
- Nivestym

Product Name: PREFERRED: Neupogen, Nivestym, Nyvepria, Udenyca, Udenyca Onbody, Ziextenzo	
Diagnosis	Neutropenia Associated with Cancer Chemotherapy –Dose Dense Chemotherapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON PREFERRED: Fulphilia, Leukine, Neulasta, Neulasta Onpro, Zarxio	
Diagnosis	Neutropenia Associated with Cancer Chemotherapy –Dose Dense Chemotherapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Neupogen
- Nivestym
- Nyvepria
- Udenyca or Udenyca Onbody
- Ziextenzo

Product Name: PREFERRED: Fylnetra, Neupogen, Nivestym, Nyvepria, Udenyca, Udenyca Onbody, Ziextenzo	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20 percent incidence of febrile neutropenia (FN)

OR

1.2 BOTH of the following:

- Patient is receiving chemotherapy regimen(s) associated with 10-20 percent incidence of FN
- Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Fulphila, Granix, Neulasta, Neulasta Onpro, Rolvedon, Stimufend, Zarxio	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20 percent incidence of febrile neutropenia (FN)

OR

1.2 BOTH of the following:

- Patient is receiving chemotherapy regimen(s) associated with 10-20 percent incidence of FN
- Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Fylnetra
- Neupogen
- Nivestym
- Nyvepria
- Udenyca or Udenyca Onbody

- Ziextenzo

Product Name: PREFERRED: Neupogen, Nivestym, Nyvepria, Udenyca, Udenyca Onbody, Ziextenzo	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Patient has a history of febrile neutropenia (FN) during a previous course of chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Fulphila, Granix, Neulasta, Neulasta Onpro, Stimufend, Zarxio	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Patient has a history of febrile neutropenia (FN) during a previous course of chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Neupogen
- Nivestym
- Nyvepria
- Udenyca or Udenyca Onbody
- Ziextenzo

Product Name: PREFERRED: Fylnetra, Neupogen, Nivestym, Nyvepria, Udenyca, Udenyca Onbody, Ziextenzo	
Diagnosis	Treatment of Febrile Neutropenia (FN) (off-label)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Diagnosis of febrile neutropenia (FN) and patient is considered high risk for infection-associated complications

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Fulphila, Leukine, Neulasta, Neulasta Onpro, Stimufend, Zarxio	
Diagnosis	Treatment of Febrile Neutropenia (FN) (off-label)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Diagnosis of febrile neutropenia (FN) and patient is considered high risk for infection-associated complications

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Fylnetra
- Neupogen
- Nivestym
- Nyvepria
- Udenyca or Udenyca Onbody
- Ziextenzo

Product Name: PREFERRED: Neupogen, Nivestym	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to BOTH of the following:

- Neupogen
- Nivestym

Product Name: PREFERRED: Neupogen, Nivestym	
Diagnosis	HIV-Related Neutropenia (off-label)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV) infection

AND

2 - Patient has an absolute neutrophil count (ANC) less than or equal to 1,000 cells per mm3

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist
- Infectious disease specialist

Product Name: NON PREFERRED: Leukine, Zarxio	
Diagnosis	HIV-Related Neutropenia (off-label)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV) infection

AND

2 - Patient has an absolute neutrophil count (ANC) less than or equal to 1,000 cells per mm3

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist
- Infectious disease specialist

AND

4 - Patient has a history of failure, contraindication, or intolerance to BOTH of the following:

- Neupogen
- Nivestym

Product Name: PREFERRED: Neupogen, Nivestym	
Diagnosis	Hepatitis C Treatment Related Neutropenia (off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

- Diagnosis of hepatitis C virus
- Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

- Documentation of neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3) after dose reduction of Peg-Intron or Pegasys

OR

1.2 BOTH of the following:

1.2.1 Documentation of interferon-induced neutropenia (ANC less than or equal to 500 cells per mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 ONE of the following:

- Diagnosis of human immunodeficiency virus (HIV) co-infection
- Status post liver transplant
- Diagnosis of established cirrhosis

AND

2 - Prescribed by, or in consultation with, a hematologist, oncologist, gastroenterologist, hepatologist, or infectious disease specialist

Product Name: NON-PREFERRED: Zarxio	
Diagnosis	Hepatitis C Treatment Related Neutropenia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

- Diagnosis of hepatitis C virus
- Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

- Documentation of neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3) after dose reduction of Peg-Intron or Pegasys

OR

1.2 BOTH of the following:

1.2.1 Documentation of interferon-induced neutropenia (ANC less than or equal to 500 cells per mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 ONE of the following:

- Diagnosis of human immunodeficiency virus (HIV) co-infection
- Status post liver transplant
- Diagnosis of established cirrhosis

AND

2 - Prescribed by, or in consultation with, a hematologist, oncologist, gastroenterologist, hepatologist, or infectious disease specialist

AND

3 - Patient has a history of failure, contraindication, or intolerance to BOTH of the following:

- Neupogen
- Nivestym

Product Name: PREFERRED: Fylnetra, Neupogen, Nivestym, Nyvepria, Udenyca, Udenyca Onbody, Ziextenzo	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: NON-PREFERRED: Fulphila, Leukine, Neulasta, Neulasta Onpro, Stimufend, Zarxio	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Fylnetra
- Neupogen
- Nivestym
- Nyvepria
- Udenyca or Udenyca Onbody
- Ziextenzo

2 . Revision History

Date	Notes
3/28/2024	Updated guideline based on new preferred agents effective 4.1.24: N eupogen, Nyvepria, Udenyca, Udenyca Onbody.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99510
Guideline Name	Combination Basal Insulin/GLP-1 Receptor Agonist
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Soliqua	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Inadequately controlled on BOTH of the following

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g. Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
- Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

Product Name: Xultophy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - Inadequately controlled on BOTH of the following

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g. Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
- Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

AND

3 - History of failure, intolerance, or contraindication to Soliqua

Product Name: Xultophy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xultophy therapy

2 . Revision History

Date	Notes
5/24/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-139359
Guideline Name	Compounds and Bulk Powders
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Requests for Compounds or Bulk Powders	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 The compound is an antibiotic.

OR

1.2 Each active ingredient in the compounded drug is a covered medication

AND

2 - ONE of the following:

2.1 Each active ingredient in the compounded drug is to be administered for an FDA (Food and Drug Administration)-approved indication

OR

2.2 The use of each active ingredient in the compounded drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons.

AND

5 - ONE of the following:

5.1 A unique vehicle is required for topically administered compounds

OR

5.2 A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form

OR

5.3 A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

OR

5.4 There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP Current Drug Shortages tracking log

AND

6 - Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 For topical compound preparations (e.g. creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use (see Table 1 in Background section)

OR

6.2 If the requested compound contains topical fluticasone, topical fluticasone will NOT be approved unless both of the following are met:

6.2.1 Topical fluticasone is intended to treat a dermatologic condition (scar treatments are considered cosmetic and will not be covered)

AND

6.2.2 Patient has a contraindication to all commercially available topical fluticasone formulations

OR

6.3 Requested compound contains any ingredients when used for cosmetic purposes (see Table 2 in Background section)

OR

6.4 Requested compound contains any ingredient(s) which are on the FDA's Do Not Compound List (see Table 3 in Background section)

Product Name: Requests for Compounds or Bulk Powders	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Administrative

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information

Table 1: Example topical compound preparations that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

(1) Ketamine

(2) Gabapentin

(3) Flurbiprofen (topical ophthalmic use not included)

(4) Ketoprofen

(5) Morphine

(6) Nabumetone

(7) Oxycodone

(8) Cyclobenzaprine

(9) Baclofen

(10) Tramadol

(11) Hydrocodone

(12) Meloxicam

(13) Amitriptyline

(14) Pentoxifylline

(15) Orphenadrine

(16) Piroxicam

(17) Levocetirizine

(18) Amantadine

(19) Oxytocin

(20) Sumatriptan

(21) Chorionic gonadotropin (human)

(22) Clomipramine

(23) Dexamethasone

(24) Hydromorphone

(25) Methadone

(26) Papaverine

(27) Mefenamic acid

(28) Promethazine

(29) Succimer DMSA

(30) Tizanidine

(31) Apomorphine

(32) Carbamazepine

(33) Ketorolac

(34) Dimercaptopropane-sulfonate

(35) Dimercaptosuccinic acid

(36) Duloxetine

(37) Fluoxetine

(38) Bromfenac (topical ophthalmic use not included)

(39) Nepafenac (topical ophthalmic use not included)

Table 2: Example compounds that contain ingredients for cosmetic purposes:

(1) Hydroquinone

(2) Acetyl hexapeptide-8

(3) Tocopheryl Acid Succinate

(4) PracaSil TM-Plus

(5) Chrysaderm Day Cream

(6) Chrysaderm Night Cream

(7) PCCA Spira-Wash

(8) Lipopen Ultra

(9) Versapro

(10) Fluticasone

(11) Mometasone

(12) Halobetasol

(13) Betamethasone

(14) Clobetasol

(15) Triamcinolone

(16) Minoxidil

(17) Tretinoin

(18) Dexamethasone

(19) Spironolactone

(20) Cycloserine

(21) Tamoxifen

(22) Sermorelin

(23) Mederma Cream

(24) PCCA Cosmetic HRT Base

(25) Sanare Scar Therapy Cream

(26) Scarcin Cream

(27) Apothederm

(28) Stera Cream

(29) Copasil

(30) Collagenase

(31) Arbutin Alpha

(32) Nourisil

(33) Freedom Cepapro

(34) Freedom Silomac Andydrous

(35) Retinaldehyde

(36) Apothederm

Table 3: Example ingredients on the FDA's Do Not Compound List:

(1) 3,3′,4′,5-tetrachlorosalicylanilide

(2) Adenosine phosphate

(3) Adrenal cortex

(4) Alatrofloxacin mesylate

(5) Aminopyrine

(6) Astemizole

(7) Azaribine

(8) Benoxaprofen

(9) Bithionol

(10) Camphorated oil

(11) Carbetapentane citrate

(12) Casein, iodinated

(13) Cerivastatin sodium

(14) Chlormadinone acetate

(15) Chloroform

(16) Cisapride

(17) Defenfluramine hydrochloride

(18) Diamthazole dihydrochloride

(19) Dibromsalan

(20) Dihydrostreptomycin sulfate

(21) Dipyrone

(22) Encainide hydrochloride

(23) Etretinate

(24) Fenfluramine hydrochloride

(25) Flosequinan

(26) Glycerol, iodinated

(27) Grepafloxacin

(28) Mepazine

(29) Metabromsalan

(30) Methapyrilene

(31) Methopholine

(32) Methoxyflurane

(33) Mibefradil dihydrochloride

(34) Nomifensine maleate

(35) Novobiocin sodium

(36) Oxyphenisatin acetate

(37) Oxyphenisatin

(38) Pemoline

(39) Pergolide mesylate

(40) Phenacetin

(41) Phenformin hydrochloride

(42) Phenylpropanolamine

(43) Pipamazine

(44) Potassium arsenite

(45) Propoxyphene

(46) Rapacuronium bromide

(47) Rofecoxib

(48) Sibutramine hydrochloride

(49) Sparteine sulfate

(50) Sulfadimethoxine

(51) Sweet spirits of nitre

(52) Tegaserod maleate

(53) Temafloxacin hydrochloride

(54) Terfenadine

(55) Ticrynafen

(56) Tribromsalan

(57) Trichloroethane

(58) Troglitazone

(59) Trovafloxacin mesylate:

(60) Urethane

(61) Valdecoxib

(62) Zomepirac sodium

3 . Revision History

Date	Notes
1/23/2024	Changed initial approval duration to 6 months and added reauth with 12 month approval duration.

Prior Authorization Guideline

Guideline ID	GL-131944
Guideline Name	Constipation Agents - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Brand Amitiza, generic lubiprostone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ONE of the following diagnoses:

- Opioid-induced constipation in an adult with chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

- Chronic idiopathic constipation

OR

1.2 Both of the following:

- Diagnosis of irritable bowel syndrome with constipation
- Patient was female at birth

AND

2 - BOTH of the following:

2.1 Trial and failure, contraindication, or intolerance to an osmotic laxative e.g., (lactulose, polyethylene glycol, sorbitol)

AND

2.2 Trial and failure, contraindication, or intolerance to ONE of the following:

- Bulk Forming Laxatives (e.g., psyllium, fiber)
- Stimulant Laxatives (e.g., bisacodyl, senna)

Product Name: Ibsrela	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - History of failure, contraindication or intolerance to ONE of the following:

- Lubiprostone
- Linzess

Product Name: Linzess	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 One of the following diagnoses:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

1.1.2 Patient is greater than or equal to 18 years of age

OR

1.2 Both of the following (Applies to Linzess 72mg requests ONLY)

- Diagnosis of functional constipation
- Patient is 6-17 years of age

AND

2 - Both of the following:

2.1 Trial and failure, contraindication, or intolerance to an osmotic laxative e.g., (lactulose, polyethylene glycol, sorbitol)

AND

2.2 Trial and failure, contraindication, or intolerance to ONE of the following:

- Bulk Forming Laxatives (e.g., psyllium, fiber)
- Stimulant Laxatives (e.g., bisacodyl, senna)

Product Name: Motegrity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic constipation

AND

2 - Both of the following

2.1 History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

2.2 History of failure, contraindication, or intolerance to BOTH of the following:

- Linzess
- Lubiprostone

Product Name: Movantik	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Opioid-induced constipation in patients being treated for chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

Product Name: Relistor tablet, Relistor injection, Symproic	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Opioid-induced constipation in patients being treated for chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - History of failure, contraindication or intolerance to Movantik

AND

4 - For Relistor Injection requests ONLY: The patient is not able to swallow oral medications

Product Name: Trulance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

2 - Patient is greater than or equal to 18 years of age

Product Name: Zelnorm	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - Patient was female at birth

AND

3 - History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

4 - History of failure, contraindication or intolerance to ONE of the following:

- Lubiprostone
- Linzess

Product Name: Brand Amitiza, generic lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Relistor tablet, Relistor injection, Symproic, Trulance, Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/29/2023	Added criteria for Linzess 72mg new indication of functional constipation.

Prior Authorization Guideline

Guideline ID	GL-144859
Guideline Name	Continuous Blood Glucose Monitoring Devices (CGM)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/27/2024

1 . Criteria

Product Name: PREFERRED Continuous Glucose Monitors, Sensors, and Transmitters: Freestyle Libre receiver, Freestyle Libre 14 receiver/sensor, Freestyle Libre 2 receiver/sensor, Freestyle Libre 3 sensor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes) documenting member is already established on an integrated closed loop insulin pump system. The current CGM product will

be approved* (NOTE: Members starting on a closed loop insulin pump system will be required to obtain a new PA if they are changing CGM devices)

OR

1.2 Member is insulin dependent as confirmed by paid claims for insulin within the past 60 days and the request is for a Freestyle Libre product (Freestyle Libre products will adjudicate without a prior authorization submission when the member is insulin dependent as confirmed by insulin paid claims in the members PBM profile)

OR

1.3 Submission of medical records (e.g., chart notes, lab results) documenting all of the following:

1.3.1 One of the following:

1.3.1.1 All of the following:

- Diagnosis of Type I or II Diabetes Mellitus
- Member is insulin dependent as demonstrated by paid claims within the past 60 days
- Frequent insulin adjustments are required based on the results of blood glucose monitoring or CGM testing results and supporting documentation has been submitted by provider

OR

1.3.1.2 One of the following diagnoses:

- Gestational Diabetes
- Hypoglycemia Unawareness (HU) (defined as the onset of neuroglycopenia, low blood glucose in the brain, before the appearance of autonomic warning symptoms, or the failure to sense a significant fall in blood glucose below normal levels) (submission of medical records/supporting documentation is required)
- Documented Postprandial Hyperglycemia (submission of medical records/supporting documentation is required)
- Documented Recurrent Diabetic Ketoacidosis (submission of medical records/supporting documentation is required)

OR

1.3.1.3 Member requires short term use (72 hours) to determine baseline insulin levels prior to insulin pump initiation

AND

1.3.2 Member must meet the FDA approved age for the requested product (new products entering the market shall not be approved below the FDA approved age)

AND

1.3.3 One of the following:

- Hemoglobin A1c > 7.0%
- Frequent hypoglycemic episodes as evidenced by submitted chart documentation
- Member has a diagnosis that is not defined by elevated hemoglobin A1c or frequent hypoglycemia (e.g., Gestational Diabetes)

AND

1.3.4 Provider attests member is enrolled or has completed a comprehensive diabetes education program

Notes	*NOTE: Members starting on a closed loop insulin pump system will b e required to obtain a new PA if they are changing CGM devices. **Third Party Exception Flag must be flipped to = Y for the claim to pa y with the PA in place. Please run a trial claim to make sure claim pay s with PA ***Approve Freestyle Libre products at NDC Level – With NDC List AZ MFR3 (see background section for details)

Product Name: NONPREFERRED Continuous Glucose Monitors, Sensors, and Transmitters: Dexcom G6 receiver/sensor/transmitter, Dexcom G7 receiver/sensor, Guardian receiver/sensor/transmitter, Enlite sensor, Eversense sensor/transmitter, Minilink transmitter, Minimed 630G Guardian transmitter, Paradigm transmitter	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes) documenting member is already established on an integrated closed loop insulin pump system. The current CGM product will be approved* (NOTE: Members starting on a closed loop insulin pump system will be required to obtain a new PA if they are changing CGM devices)

OR

1.2 Submission of medical records (e.g., chart notes, lab results) documenting all of the following:

1.2.1 One of the following:

1.2.1.1 All of the following:

- Diagnosis of Type I or II Diabetes Mellitus
- Member is insulin dependent as demonstrated by paid claims within the past 60 days
- Frequent insulin adjustments are required based on the results of blood glucose monitoring or CGM testing results and supporting documentation has been submitted by the provider

OR

1.2.1.2 One of the following diagnoses:

- Gestational Diabetes
- Hypoglycemia Unawareness (HU) (defined as the onset of neuroglycopenia, low blood glucose in the brain, before the appearance of autonomic warning symptoms, or the failure to sense a significant fall in blood glucose below normal levels) (submission of medical records/supporting documentation is required)
- Documented Postprandial Hyperglycemia (submission of medical records/supporting documentation is required)
- Documented Recurrent Diabetic Ketoacidosis (submission of medical records/supporting documentation is required)

OR

1.2.1.3 Member requires short term use (72 hours) to determine baseline insulin levels prior to insulin pump initiation

AND

1.2.2 Member must meet the FDA approved age for the requested product (new products entering the market shall not be approved below the FDA approved age)

AND

1.2.3 One of the following:

- Hemoglobin A1c > 7.0%
- Frequent hypoglycemic episodes as evidenced by submitted chart documentation
- Member has a diagnosis that is not defined by elevated hemoglobin A1c or frequent hypoglycemia (e.g., Gestational Diabetes)

AND

1.2.4 Provider attests member is enrolled or has completed a comprehensive diabetes education program

AND

1.2.5 Member has tried and failed the Freestyle Libre system (For other AHCCCS Contractors required steps, please refer to Preferred CGM Products table)

Notes	*NOTE: Members starting on a closed loop insulin pump system will b e required to obtain a new PA if they are changing CGM devices **Third Party Exception Flag must be flipped to = Y for the claim to pa y with the PA in place. Please run a trial claim to make sure claim pay s with PA ***Approve all NonPreferred CGM products at GPI Level – With GPI L ist AZMCGMNP (see background section for details)

Product Name: ALL Continuous Glucose Monitors, Sensors, and Transmitters: Freestyle Libre receiver, Freestyle Libre 14 receiver/sensor, Freestyle Libre 2 receiver/sensor, Freestyle Libre

3 sensor, Dexcom G6 receiver/sensor/transmitter, Dexcom G7 receiver/sensor, Guardian receiver/sensor/transmitter, Enlite sensor, Eversense sensor/transmitter, Minilink transmitter, Minimed 630G Guardian transmitter, Paradigm transmitter	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is using the same continuous glucose monitoring device on a regular basis as evidenced through the Member's claims history and the providers chart notes

AND

2 - Member is adherent to using the device

AND

3 - Member has shared the device readings with physician or healthcare professional for review as part of overall diabetes management

Notes	Third Party Exception Flag must be flipped to = Y for the claim to pay with the PA in place. Please run a trial claim to make sure claim pays with PA Approve all Preferred Freestyle Libre products at NDC Level - With N DC List AZMFR3 Approve all NonPreferred CGM products at GPI Level – With GPI List AZMCGMNP (see background section for details)

Product Name: ALL Continuous Glucose Monitors, Sensors, and Transmitters: Freestyle Libre receiver, Freestyle Libre 14 receiver/sensor, Freestyle Libre 2 receiver/sensor, Freestyle Libre 3 sensor, Dexcom G6 receiver/sensor/transmitter, Dexcom G7 receiver/sensor, Guardian receiver/sensor/transmitter, Enlite sensor, Eversense sensor/transmitter, Minilink transmitter, Minimed 630G Guardian transmitter, Paradigm transmitter	
Diagnosis	Requests Exceeding Quantity Limit
Approval Length	1 Time(s)

Guideline Type	Quantity Limit
Approval Criteria **1** - Request is for a vacation override **OR** **2** - If not for a vacation override, requests for additional transmitter/sensor quantities should be denied • Dexcom 6 or 7 sensors: The plan covers a maximum of 3 sensors for a 30 day supply. For defective products, please contact Dexcom CARE at 1-888-738-3646 for a replacement. • For FreeStyle Libre 2 or 3 sensors – The plan covers a maximum of 2 sensors for a 28-day supply. For defective products, please contact FreeStyle Libre Customer Support at 1-844-330-5535 for a replacement. • Guardian Sensor 3 or 4 products – The plan covers a maximum of 5 sensors (1box) for a 35-day supply. For defective products, please contact the Guardian Customer Service Center at 1-800-646-4633 for a replacement.	
Notes	*Requests for additional quantities for purposes other than a vacation override are to be denied, utilize the product specific denial verbiage b elow. Third Party Exception Flag must be flipped to = Y for the claim t o pay with the PA in place. Please run a trial claim to ensure the claim adjudicates with PA Approve at NDC/GPI Level. Denial language: ● Dexcom 6 or 7 transmitters - The prior authorization request for mor e than 1 transmitter in 90 days are to be denied. The plan covers a m aximum of 1 transmitter for a 90-day supply. If the member has a defe ctive transmitter, please contact Dexcom CARE at 1- 888-738-3646 fo r a replacement. ● Dexcom 6 or 7 sensors - The prior authorization request for more th an 3 sensors in 30 days are to be denied. The plan covers a maximu m of 3 sensors for a 30-day supply. If the member has a defective sen sor, please contact Dexcom CARE at 1-888-738-3646 for a replacem ent. ● Dexcom G6 Receiver - The prior authorization request for more tha n 1 receiver in 365 days are to be denied. The plan covers a maximu m of 1 transmitter for a 365-day supply. If the member has a defective receiver, please contact Dexcom CARE at 1- 888-738-3646 for a repl acement. FreeStyle Libre & FreeStyle Libre 2 & 3 sensors - The prior authorization request for more than 2 sensors, for a 28-day

	supply, are to be denied. ● The plan covers a maximum of 2 sensors for a 28-Day supply. If yo u have a defective a sensor, please contact Abbott's FreeStyle Libre Customer Support at 1-844-330-5535 for a replacement. Guardian Sensor 3 or 4 Sensors – The plan covers a maximum of 5 sensors (1 box) for a 35-day supply. For defective products, please contact the Guardian Customer Servic e Center at 1-800-646-4633 for a replacement.

2 . Background

Benefit/Coverage/Program Information

Preferred CGM Products

Health Plan	CGM Step Therapy Requirements
Arizona Complete Health	**Freestyle Libre 2 & 3**
Banner University Family Care	**Freestyle Libre 2 & 3**
Care 1st Health Plan	**Freestyle Libre 2 & 3**
DCS Comprehensive Health Plan	**Dexcom G6 & G7** **Freestyle Libre 2 & 3**
Division of Developmental Disabilities	**Freestyle Libre 2 & 3**
AHCCCS Fee-For-Service American Indian Health Plan	**Freestyle Libre 2 & 3**
Health Choice Arizona	**Freestyle Libre 2 & 3**
Mercy Care	**Dexcom G6 & G7** **Freestyle Libre 2 & 3**
Molina Healthcare	**Dexcom G6 & G7** **Freestyle Libre 2 & 3**
United Community Plan	**Dexcom G6 & G7** **Freestyle Libre 2 & 3**

NDC List for Preferred CGM Products

NDC List	NDC	Product Label	GPI	GPI-14 Description
AZMFR3	57599080300	FREESTY LIBR MIS 2 READER	97202012026200	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***
AZMFR3	57599000021	FREESTYLE MIS READER	97202012026200	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***
AZMFR3	57599000200	FREESTYLE MIS READER	97202012026200	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***
AZMFR3	57599082000	FREESTY LIBR MIS 3 READER	97202012046300	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***
AZMFR3	57599081800	FREESTY LIBR KIT 3 SENSOR	97202012046300	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***
AZMFR3	57599080000	FREESTY LIBR KIT 2 SENSOR	97202012046300	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***
AZMFR3	57599000101	FREESTYLE KIT SENSOR	97202012046300	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***

Third Party Exception Flag must be flipped to = Y for the claim to pay with the PA in place. Please run a trial claim to make sure claim pays with PA

GPI Lists for NonPreferred CGM Products

GPI List	GPI	GPI-14 Description
AZMCGMNP	97202012026200	*CONTINUOUS BLOOD GLUCOSE SYSTEM RECEIVER***
AZMCGMNP	97202012046300	*CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***
AZMCGMNP	97202012066300	*CONTINUOUS BLOOD GLUCOSE SYSTEM TRANSMITTER***

Third Party Exception Flag must be flipped to = Y for the claim to pay with the PA in place. Please run a trial claim to make sure claim pays with PA

Notes

Third Party Exception Flag must be flipped to = Y for the claim to pay with the PA in place. Please run a trial claim to make sure claim pays with PA

Coverage Notes:

AHCCCS Rule R9-22-202 requires that services be cost effective. The corresponding federal regulations are found in 42 CFR Part 447

R9-22-202. General Requirements

B. In addition to other requirements and limitations specified in this Chapter, the following general requirements apply: Only medically necessary, cost effective, and federally reimbursable and state-reimbursable services are covered.

3 . Revision History

Date	Notes

3/26/2024	Added GPI for Libre 3, updated NDC list table.

Prior Authorization Guideline

Guideline ID	GL-135313
Guideline Name	Copper Chelating Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe active rheumatoid arthritis	

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Depen Titratabs therapy

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)
- Diagnosis of Cystinuria

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Wilson's disease (i.e., hepatolenticular degeneration)
- Cystinuria

- Severe active rheumatoid arthritis

AND

2 - History of failure or intolerance to Depen (penicillamine)

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cuprimine (penicillamine) therapy

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - History of failure, contraindication, or intolerance to Depen (penicillamine) or Cuprimine (penicillamine)

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson’s disease (i.e., hepatolenticular degeneration)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Syprine (trientine) therapy	

2 . Revision History

Date	Notes
10/23/2023	Added new GPI for trientine

Prior Authorization Guideline

Guideline ID	GL-99441
Guideline Name	Corlanor
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Worsening heart failure in a diagnosis of stable, symptomatic chronic (e.g. New York Heart Association (NYHA) class II, III or IV) heart failure

AND

2 - Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

AND

3 - The patient is in sinus rhythm

AND

4 - Patient has a resting heart rate greater than or equal to 70 beats per minute

AND

5 - ONE of the following:

5.1 Patient is on maximum tolerated doses of beta blockers (e.g., carvedilol, metoprolol succinate, bisoprolol)

OR

5.2 Patient has a contraindication or intolerance to beta-blocker therapy

Product Name: Corlanor	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy (DCM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)

AND

2 - Patient is in sinus rhythm

AND

3 - Patient has an elevated heart rate

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure, Heart Failure due to Dilated Cardiomyopathy (DCM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Corlanor therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy guidelines starting with B and C from C&S Arizona to Ariz ona Medicaid

Prior Authorization Guideline

Guideline ID	GL-140222
Guideline Name	Cosentyx (secukinumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 Both of the following:

1.3.1 History of failure to TWO of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Otezla (apremilast)

AND

2 - Patient is 6 years of age or older

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC, Cosentyx IV	
Diagnosis	Ankylosing Spondylitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following:*

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes) or paid claims documenting history of failure to self-administered Cosentyx SC (APPLIES TO REQUESTS FOR COSENTYX IV ONLY):

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC, Cosentyx IV	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC, Cosentyx IV	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.3 History of failure, contraindication, or intolerance to THREE of the following*:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Patient is 2 years of age or older

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

AND

4 - Submission of medical records (e.g., chart notes) or paid claims documenting history of

failure to self-administered Cosentyx SC (APPLIES TO REQUESTS FOR COSENTYX IV ONLY):

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC, Cosentyx IV	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC, Cosentyx IV	
Diagnosis	Non-radiographic axial spondyloarthritis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes) or paid claims documenting history of failure to self-administered Cosentyx SC (APPLIES TO REQUESTS FOR COSENTYX IV ONLY):

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC, Cosentyx IV	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

1.1 Diagnosis of active enthesitis-related arthritis

AND

1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO preferred non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)*

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of moderate to severe hidradenitis suppurativa

AND

1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Humira*

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)

2 . Revision History

Date	Notes
1/31/2024	Update specialist in new HS indication reauth section to dermatologist (previously stated rheumatologist).

Prior Authorization Guideline

Guideline ID	GL-104889
Guideline Name	Cough and Cold Products
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/28/2022

1 . Criteria

Product Name: Hydromet, generic Tussigon, Z-Tuss AC, Tuzistra XR, Tussicaps, generic Tussionex, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss, generic promethazine w/codeine, generic promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP/Mar-Cof GG, Ninjacof-XG, Coditussin AC/Coditussin DAC, generic guaifenesin-codeine, generic pseudoephedrine w/codeine-guaifenesin, Tuxarin ER	
Diagnosis	Under the Age of 18 Years for Cough and Cold Products
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prescriber attests they are aware of Food and Drug Administration (FDA) labeled contraindications regarding use of opioid containing cough and cold products in patients less	

than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

AND

2 - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index greater than 30)

AND

3 - Patient has tried and failed at least one non-opioid containing cough and cold remedy

Product Name: Hydromet, generic Tussigon, Z-Tuss AC, Tuzistra XR, Tussicaps, generic Tussionex, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss, generic promethazine w/codeine, generic promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP/Mar-Cof GG, Ninjacof-XG, Coditussin AC/Coditussin DAC, generic guaifenesin-codeine, generic pseudoephedrine w/codeine-guaifenesin, Tuxarin ER	
Diagnosis	Quantity Limit
Approval Length	30 Day(s)
Guideline Type	Quantity Limit*

Approval Criteria

1 - Prescriber attests that a larger quantity is medically necessary

AND

2 - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (See table in background section)

Notes	*Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.

2 . Background

Benefit/Coverage/Program Information

CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Hydrocodone	None
Tapentadol	600mg IR products
Oxymorphone	None
Oxycodone	None
Codeine	360mg
Pentazocine	None
Tramadol	400mg IR products
Meperidine	600mg
Butorphanol nasal	None
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day
Acetaminophen	4g/day
Aspirin	2080mg/day
Ibuprofen	3200mg/day
Benzhydrocodone**	None

3 . Revision History

Date	Notes
3/28/2022	Updated product list, no changes to criteria.

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Prior Authorization Guideline

Guideline ID	GL-99530
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols

- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehesive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus

1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.

Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**

G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3

designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 9, 2020.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 9, 2020.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2020.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 9, 2020.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 9, 2020.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/P

FActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed September 9, 2020.

5 . Revision History

Date	Notes
5/18/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-127083
Guideline Name	Cuvrior (trientine hydrochloride)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following:

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, contraindication, or intolerance to generic penicillamine capsules

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name: Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

2 . Revision History

Date	Notes
6/26/2023	New Program

Prior Authorization Guideline

Guideline ID	GL-99663
Guideline Name	Cystaran, Cystadrops
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cystaran, Cystadrops	
Diagnosis	Cystinosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystinosis	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona Medicaid SP to Medicaid Arizona SP for eff 7 /1

Prior Authorization Guideline

Guideline ID	GL-117633
Guideline Name	Daliresp (roflumilast)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe to very severe chronic obstructive pulmonary disease (COPD) (i.e., FEV1 less than or equal to 50% of predicted)

AND

2 - COPD is associated with chronic bronchitis

AND

3 - History of COPD exacerbation(s)

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Daliresp therapy

2 . Revision History

Date	Notes
12/4/2022	Added generic roflumilast as target

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Prior Authorization Guideline

Guideline ID	GL-99605
Guideline Name	Daraprim
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical record documentation (e.g. chart notes) of one of the following:

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary Pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.4.3 ONE of the following:

1.4.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.4.3.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma immunoglobulin G (IgG) positive

AND

1.5.3 CD4 (cluster of differentiation 4) less than or equal to 100 cells per mm3 if initiating prophylaxis or CD4 100-200 cells per mm3 if reinstituting prophylaxis

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.5.6 ONE of the following:

1.5.6.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.5.6.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

Notes	*Consider discontinuation of primary prophylaxis if CD4 greater than 200 cells/mm3 for greater than 3 months after institution of combination antiretroviral therapy.

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

Guideline ID	GL-135325
Guideline Name	Daxxify (botulinum toxin type a injection)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Daxxify	
Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of cervical dystonia

Product Name: Daxxify

Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

Product Name: Daxxify	
Diagnosis	Cosmetic Use
Approval Length	N/A - requests for cosmetic use are excluded and will not be approved
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any Daxxify product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only and are excluded from coverage.

Notes	Requests for coverage of any Daxxify product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only and are excluded from coverage.

2 . Revision History

Date	Notes
10/23/2023	New program

Prior Authorization Guideline

Guideline ID	GL-125943
Guideline Name	Daybue (trofinetide)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Daybue	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Rett syndrome

AND

2 - One of the following:

2.1 Submission of medical records (e.g., chart notes) confirming presence of ALL of the following clinical signs and symptoms:

- A pattern of development, regression, then recovery or stabilization
- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

2.2 Submission of medical records (e.g., chart notes) documenting molecular genetic testing confirms mutations in the MECP2 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Geneticist
- Neurologist

Product Name: Daybue	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

2 . Revision History

Date	Notes
5/22/2023	New program

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Prior Authorization Guideline

Guideline ID	GL-105310
Guideline Name	DDAVP (desmopressin) tablets - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand DDAVP tablets, generic desmopressin acetate tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of central diabetes insipidus

OR

1.2 Diagnosis of polyuria and/or polydipsia following head trauma or surgery in the pituitary region **OR** **1.3** Diagnosis of primary nocturnal enuresis **AND** **2** - For Brand DDAVP ONLY: Trial and failure to generic desmopressin tablets (verified via paid pharmacy claims or submission of medical records)	
Notes	NOTE: Plan setup requires use of generic desmopressin tablets befor e Brand DDAVP

2 . Revision History

Date	Notes
3/29/2022	Added step through generic tablets for Brand.

Prior Authorization Guideline

Guideline ID	GL-99559
Guideline Name	Declomycin - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: demeclocycline*	
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of ONE of the following:

- Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox and tick fevers caused by rickettsiae
- Respiratory tract infections caused by Mycoplasma pneumoniae
- Lymphogranuloma venereum due to Chlamydia trachomatis
- Psittacosis (Ornithosis) due to Chlamydia psittaci
- Trachoma due to Chlamydia trachomatis

- Inclusion conjunctivitis caused by Chlamydia trachomatis
- Nongonococcal urethritis in adults caused by Ureaplasma urealyticum or Chlamydia trachomatis
- Relapsing fever due to Borrelia recurrentis
- Chancroid caused by Haemophilus ducreyi
- Plague due to Yersinia pestis
- Tularemia due to Francisella tularensis
- Cholera caused by Vibrio cholerae
- Campylobacter fetus infections cause by Campylobacter fetus
- Brucellosis due to Brucella species (in conjunction with streptomycin)
- Bartonellosis due to Bartonella bacilliformis
- Granuloma inguinale caused by Calymmatobacterium granulomatis
- Infection due to Escherichia coli
- Infection due to Enterobacter aerogenes
- Infection due to Shigella species
- Infection due to Acinetobacter species
- Respiratory tract infections caused by Haemophilus influenza
- Respiratory tract and urinary tract infections caused by Klebsiella species
- Upper respiratory infections caused by Streptococcus pneumoniae
- Skin and skin structure infections caused by Staphylococcus aureus.
- Uncomplicated urethritis in men due to Neisseria gonorrhoeae, and for the treatment of other uncomplicated gonococcal infections
- Infections in women caused by Neisseria gonorrhoeae
- Syphilis caused by Treponema pallidum subspecies pallidum
- Yaws caused by Treponema pallidum subspecies pertenue
- Listeriosis due to Listeria monocytogenes
- Anthrax due to Bacillus anthracis
- Vincent's infection caused by Fusobacterium fusiforme
- Actinomycosis caused by Actinomyces israelii
- Clostridial diseases caused by Clostridium species
- Acute intestinal amebiasis, as adjunctive therapy
- Severe acne, as adjunctive therapy

OR

1.2 The medication is being prescribed by or in consultation with an Infectious Disease specialist

Notes	*Approval duration: 6 months

2 . Revision History

Date	Notes
6/23/2021	update program

Prior Authorization Guideline

Guideline ID	GL-99444
Guideline Name	Dificid
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Dificid	
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile- associated diarrhea]

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to Firvanq (vancomycin) oral solution

OR

2.2 History of failure, contraindication, or intolerance to oral Vancocin (vancomycin) capsules or vancomycin oral solution (NOT Firvanq) if the prescriber provides a reason or special circumstance the patient cannot use Firvanq

OR

2.3 For continuation of prior Dificid therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-99445
Guideline Name	Dofetilide - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: : Brand Tikosyn, generic dofetilide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Atrial fibrillation
- Atrial flutter

AND

2 - Patient requires ONE of the following:

- Conversion to normal sinus rhythm
- Maintenance of normal sinus rhythm

AND

3 - Verification that the patient has already started on dofetilide while in the hospital for a minimum of 3 days

AND

4 - Patient does NOT have severe renal impairment [Creatinine Clearance (CrCl) less than 20 milliliters per minute]

AND

5 - Patient does NOT have congenital or acquired long QT syndromes

AND

6 - Patient is NOT concurrently using cimetidine, hydrochlorothiazide, ketoconazole, megestrol, prochlorperazine, trimethoprim, dolutegravir or verapamil

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

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Prior Authorization Guideline

Guideline ID	GL-116190
Guideline Name	Dojolvi (triheptanoin)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) has been confirmed by at least two of the following:

- Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to continued need of therapy

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

2 . Revision History

Date	Notes
10/28/2022	New Program

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Prior Authorization Guideline

Guideline ID	GL-139349
Guideline Name	DPP-4 Inhibitors - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Tradjenta, Januvia, Onglyza, Kombiglyze XR, Jentadueto, Janumet, Janumet XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 History of failure to metformin at a minimum dose of 1500 milligrams daily for 90 days

OR

2.2 Contraindication or intolerance to metformin

Product Name: alogliptin, Nesina, alogliptin/metformin, Kazano, alogliptin/pioglitazone, Oseni, Jentadueto XR, Zituvio	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 History of failure to metformin at a minimum dose of 1500 milligrams daily for 90 days

OR

2.2 Contraindication or intolerance to metformin

AND

3 - ONE of the following:

3.1 History of failure for 90 days to three of the following:

- Tradjenta
- Januvia
- Onglyza
- Kombiglyze XR

- Janumet
- Janumet XR
- Jentadueto

OR

3.2 Intolerance or contraindication to THREE of the following:

- Tradjenta
- Januvia
- Onglyza
- Kombiglyze XR
- Janumet
- Janumet XR
- Jentadueto

AND

4 - If the request is for a combination product (e.g alogliptin/metformin, alogliptin/pioglitazone), the individual products have been tried and failed.

2 . Revision History

Date	Notes
1/23/2024	Added Zituvio as NP target

Prior Authorization Guideline

Guideline ID	GL-144641
Guideline Name	Dry Eye Disease - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Preferred: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tear deficiency associated with ocular inflammation due to one of the following:

- Moderate to severe keratoconjuctivitis sicca
- Moderate to severe dry eye disease

AND

2 - Submission of medical records (e.g., chart notes) confirming diagnosis by ONE of the following diagnostic tests:

- Schirmer test
- Ocular surface dye staining (e.g., rose bengal, fluorescein, lissamine green)
- Tear function index/fluorescein clearance test
- Tear break up time
- Tear film osmolarity
- Slit lamp lid evaluation
- Lacrimal gland function

AND

3 - Medication is not being prescribed to manage dry eyes peri-operative elective eye surgery (e.g., LASIK)

AND

4 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to at least one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments) in the past 60 days

AND

5 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

AND

6 - Submission of medical records (e.g., chart notes) or paid claims confirming a minimum trial of 60 days of Brand Restasis single dose vials, unless contraindicated

Product Name: Non-Preferred: Cequa, generic cyclosporine emulsion, Miebo, Restasis MultiDose, Tyrvaya, Vevye	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tear deficiency associated with ocular inflammation due to one of the following:

- Moderate to severe keratoconjuctivitis sicca
- Moderate to severe dry eye disease

AND

2 - Submission of medical records (e.g., chart notes) confirming diagnosis by ONE of the following diagnostic tests:

- Schirmer test
- Ocular surface dye staining (e.g., rose bengal, fluorescein, lissamine green)
- Tear function index/fluorescein clearance test
- Tear break up time
- Tear film osmolarity
- Slit lamp lid evaluation
- Lacrimal gland function

AND

3 - Medication is not being prescribed to manage dry eyes peri-operative elective eye surgery (e.g., LASIK)

AND

4 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to at least one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments) in the past 60 days

AND

5 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

AND

6 - Submission of medical records (e.g., chart notes) or paid claims confirming a minimum trial of 60 days of BOTH of the following, unless contraindicated:

- Brand Restasis single dose vials
- Xiidra (PA may be required)

Product Name: Preferred: Xiidra; Non-Preferred: Cequa, generic cyclosporine emulsion, Miebo, Restasis MultiDose, Tyrvaya, Vevye	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

2 . Revision History

Date	Notes
3/27/2024	Updated criteria/preferred status from Jan P&T, Xiidra now preferred. Added Miebo, Tyrvaya and Restasis Multidose as NP targets.

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Prior Authorization Guideline

Guideline ID	GL-99563
Guideline Name	Duexis and Vimovo - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Duexis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug) induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)

- Concurrent use of anticoagulants (eg, warfarin, heparin)
- Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

AND

2 - Documentation of history of failure, contraindication, or intolerance to THREE combinations of preferred NSAIDS taken with preferred H2 (histamine 2)-receptor antagonists. (Provide name and date preferred products were tried)*

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination.

Notes	*Please reference background section for preferred products table

Product Name: Brand Vimovo, generic naproxen-esomeprazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug) induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (eg, warfarin, heparin)
- Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

AND

2 - Documentation of history of failure, contraindication, or intolerance to THREE combinations of preferred NSAIDS taken with preferred proton pump inhibitors (PPIs). (Provide name and date preferred products were tried)*

AND **3** - Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination.	
Notes	*Please reference background section for preferred products table

2 . Background

Benefit/Coverage/Program Information		
Preferred Table		
NSAIDS	**Proton Pump Inhibitors (PPIs)**	**H2 (histamine 2)-receptor antagonists**
Diclofenac DR (Generic Voltaren)	esomeprazole (Generic Nexium)	Famotidine (Generic Pepcid)
Diclofenac ER (Generic Voltaren ER)	lansoprazole (Generic Prevacid)	Nizatidine (Generic Axid)
Etodolac (Generic Lodine)	omeprazole (Generic Prilosec)	Ranitidine (Generic Zantac)
Etodolac ER (Generic Lodine ER)	pantoprazole sodium (Generic Protonix)	
Fenoprofen (Generic Nalfon)		
Flurbiprofen (Generic Ansaid)		
Ibuprofen		
Indomethacin (Generic Indocin)		

Ketorolac (Generic Toradol)		
Mefenamic (Generic Ponstel)		
Meloxicam (Generic Mobic)		
Nabumetone (Generic Relafen)		
Nabumetone DS (Generic Relafen DS)		
Naproxen (Generic Anaprox)		
Naproxen DR (Generic Anaprox DR)		
Naproxen EC (Generic Anaprox EC)		
Oxaprozin (Generic Daypro)		
Piroxicam (Generic Feldene)		
Sulindac (Generic Clinoril)		

Prior Authorization Guideline

Guideline ID	GL-99446
Guideline Name	Duopa
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Duopa	
Diagnosis	Parkinson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced Parkinson's disease

AND

2 - Patient is levodopa-responsive

AND

3 - Patient experiences disabling “off” periods for a minimum of 3 hours per day

AND

4 - Disabling “off" periods occur despite therapy with BOTH of the following:

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT [catechol-O-methyltransferase] inhibitor [entacapone, tolcapone], MAO-B [monoamine oxidase-B] inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Has undergone or has planned placement of a procedurally-placed tube

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Duopa	
Diagnosis	Parkinson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Duopa therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-143434
Guideline Name	Dupixent (dupilumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 6 months of age or older

AND

2 - Submission of documentation (e.g., chart notes) confirming ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of moderate to severe chronic atopic dermatitis

AND

2.1.2 History of failure, contraindication, or intolerance to the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of chronic atopic dermatitis that has been determined to be severe based on physician assessment

AND

2.2.2 History of failure, contraindication, or intolerance to one topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] (document drug, date of trial, and/or contraindication to medication)*

OR

2.3 Patient is currently on Dupixent therapy

AND

3 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

AND

4 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Dupixent therapy

AND

2 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

AND

3 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of moderate to severe asthma

AND

2 - Patient is 6 years of age or older

AND

3 - ONE of the following:

3.1 ALL of the following:

3.1.1 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following

- Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3.1.2 Dupixent will be used in combination with one of the following:

3.1.2.1 ONE high-dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)] (see Table 2 in Background section)

OR

3.1.2.2 Combination therapy including BOTH of the following:

3.1.2.2.1 ONE high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)] (see Table 2 in Background section)

AND

3.1.2.2.2 ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

3.1.3 ONE of the following:

3.1.3.1 Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter within the past 6 weeks

OR

3.1.3.2 Patient is currently dependent on oral corticosteroids for the treatment of asthma

OR

3.2 Patient is currently on Dupixent therapy

AND

4 - Patient is NOT receiving Dupixent in combination with ONE of the following:

- Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g. Xolair (omalizumab)]

AND

5 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent is being used in combination with an inhaled corticosteroid (ICS)-containing controller medication (see Table 2 in Background section)

AND

3 - Patient is NOT receiving Dupixent in combination with ONE of the following:

- Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g. Xolair (omalizumab)]

AND

4 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Submission of documentation (e.g., chart notes) confirming ONE of the following:

2.1 ALL of the following:

2.1.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:

2.1.1.1 TWO or more of the following symptoms for greater than or equal to 12 weeks duration:

- Mucopurulent discharge
- Nasal obstruction and congestion
- Decreased or absent sense of smell
- Facial pressure or pain

AND

2.1.1.2 ONE of the following:

- Evidence of inflammation on paranasal sinus examination or computed tomography (CT)
- Evidence of purulence coming from paranasal sinuses or ostiomeatal complex

AND

2.1.1.3 The presence of nasal polyps

AND

2.1.2 ONE of the following:

- Patient has required prior sino-nasal surgery
- Patient has required systemic corticosteroids in the previous 2 years

AND

2.1.3 Patient has been unable to obtain symptom relief after trial of ALL of the following agents/classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g. fluticasone, mometasone, triamcinolone, etc.)

- Antileukotriene agents (e.g. montelukast, zafirlukast, zileuton)

OR

2.2 ALL of the following:

2.2.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2.2.2 Patient is currently on Dupixent therapy

AND

3 - Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

AND

4 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

5 - Prescribed by one of the following:

- Otolaryngologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Dupixent therapy

AND

2 - Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

AND

3 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

4 - Prescribed by one of the following:

- Otolaryngologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain)

AND

3 - Submission of documentation (e.g., chart notes, lab values) confirming patient has at least 15 intraepithelial eosinophils per high power field (HPF)

AND

4 - Other causes of esophageal eosinophilia have been excluded

AND

5 - Both of the following:

- Patient is at least 1 year of age
- Patient weighs at least 15 kg

AND

6 - Paid claims or submission of documentation (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

7 - Prescribed by one of the following:

- Gastroenterologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline:

- Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

AND

2 - Prescribed by one of the following:

- Gastroenterologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Trial and failure, contraindication, or intolerance to one previous PN treatment (e.g., topical corticosteroids, topical calcineurin inhibitors [pimecrolimus, tacrolimus], topical capsaicin)

AND

4 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to therapy as evidenced by improvement of at least one of the following:

- Reduction in the number of nodular lesions from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05

	tridifloronide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids Adults and adolescents (12 years of age and older)

Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	N/A	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

3 . Revision History

Date	Notes
2/26/2024	Updated age/weight criterion for EoE indication due to expanded app roval.

Prior Authorization Guideline

Guideline ID	GL-99567
Guideline Name	Durezol
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Durezol	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to BOTH of the following:

- prednisolone 1%
- dexamethasone ophthalmic drops and/or ointment.

2 . Revision History

Date	Notes
7/8/2021	Changed approval length to 2 months

Prior Authorization Guideline

Guideline ID	GL-99550
Guideline Name	Ecoza (econazole)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Ecoza, Generic econazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- butenafine
- ciclopirox
- clotrimazole

- clotrimazole w/ betamethasone
- ketoconazole
- miconazole
- nystatin
- terbinafine
- tolnaftate

2 . Revision History

Date	Notes
6/10/2021	Update guideline

Prior Authorization Guideline

Guideline ID	GL-99606
Guideline Name	Egrifta
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Egrifta SV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy	

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

Guideline ID	GL-99607
Guideline Name	Elaprase - Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Elaprase	
Diagnosis	Hunter syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

Guideline ID	GL-99447
Guideline Name	Elidel-Protopic
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Elidel, generic pimecrolimus, Brand Protopic 0.03%, generic tacrolimus 0.03%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 2 years of age or older

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid in the past 90 days

OR

2.2 Drug is being prescribed for the facial or groin area

Product Name: Brand Protopic 0.1%, generic tacrolimus 0.1%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 16 years of age or older

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid in the past 90 days

OR

2.2 Drug is being prescribed for the facial or groin area

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-99448
Guideline Name	Elmiron
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Elmiron	
Diagnosis	Bladder pain or discomfort associated with interstitial cystitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-144631
Guideline Name	Emflaza (deflazacort)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Brand Emflaza, generic deflazacort	
Diagnosis	Duchenne Muscular Dystrophy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy

AND

2 - Patient is 2 years of age or older

AND

3 - History of failure, contraindication, or intolerance to ONE of the following for the treatment of Duchenne muscular dystrophy:

- Prednisone
- Prednisolone

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - If the request is for generic deflazacort, patient must have tried and failed Brand Emflaza

Product Name: Brand Emflaza, generic deflazacort	
Diagnosis	Duchenne Muscular Dystrophy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician attestation that the patient has had a positive clinical response to therapy

AND

2 - If the request is for generic deflazacort, patient must have tried and failed Brand Emflaza

2 . Revision History

Date	Notes
3/19/2024	Updated guideline name, added step through preferred Brand Emflaz a for generic deflazacort

Prior Authorization Guideline

Guideline ID	GL-139348
Guideline Name	Enbrel (etanercept)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Rheumatoid Arthritis (RA)

AND

2 - History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is 2 years of age or older

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Active Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Active Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Enbrel	
Diagnosis	Moderate to Severe Chronic Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Moderate to Severe Chronic Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Ankylosing spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - History of failure to two non-steroidal anti-inflammatory drugs (NSAIDs: e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes

1/26/2024	Added age criteria for PJIA indication, removed concomitant use safe ty criterion from all sections

Prior Authorization Guideline

Guideline ID	GL-99450
Guideline Name	Endari
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of sickle cell disease
- Used to reduce acute complications of sickle cell disease

AND

2 - ONE of the following:

- Patient is using Endari with concurrent hydroxyurea therapy
- Patient is unable to take hydroxyurea due to a contraindication or intolerance

AND

3 - Patient has had 2 or more painful sickle cell crises within the past 12 months

Product Name: Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Endari therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

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Prior Authorization Guideline

Guideline ID	GL-123730
Guideline Name	Enjaymo (sutimlimab-jome)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Enjaymo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of cold agglutinin disease (CAD) based on ALL of the following:

- Presence of chronic hemolysis (e.g., bilirubin level above the normal reference range, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count)
- Positive polyspecific direct antiglobulin test (DAT)

- Monospecific DAT strongly positive for C3d
- Cold agglutinin titer greater than or equal to 64 measured at 4 degree celsius
- Direct antiglobulin test (DAT) result for Immunoglobulin G (IgG) of 1 plus or less

AND

2 - Patient does not have cold agglutinin syndrome secondary to other factors (e.g., overt hematologic malignancy, primary immunodeficiency, infection, rheumatologic disease, systemic lupus erythematosus or other autoimmune disorders)

AND

3 - Baseline hemoglobin level less than or equal to 10.0 gram per deciliter (g/dL)

AND

4 - One of the following:

- Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg
- Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater

AND

5 - Prescribed by or in consultation with a hematologist

Product Name: Enjaymo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) demonstrating positive clinical response to therapy as evidenced by ALL of the following:

- The patient has not required any blood transfusions after the first 5 weeks of therapy with Enjaymo
- Hemoglobin level greater than or equal to 12 gram per deciliter (g/dL) or increased greater than or equal to 2 g/dL from baseline

AND

2 - One of the following:

- Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg
- Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater

AND

3 - Prescribed by or in consultation with a hematologist

2 . Background

Clinical Practice Guidelines

Weight-Based Dosing

The dosing is 6,500mg or 7,500mg Enjaymo (based on body weight) intravenously over approximately 60 minutes on Day 0, Day 7, and every 14 days thereafter	
Body Weight Range	Dose
39kg to less than 75kg	6,500 mg
75kg or greater	7,500 mg

3 . Revision History

Date	Notes

3/23/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99451
Guideline Name	Entocort EC
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Entocort EC, generic budesonide	
Diagnosis	Chrohn's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Entocort EC is being used for the treatment of Crohn's disease	

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-99452
Guideline Name	Entresto
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Entresto	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - As continuation of therapy initiated during an inpatient stay

OR

2 - Both of the following:

2.1 Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic

AND

2.2 Prescribed by or in consultation with a cardiologist

OR

3 - ALL of the following:

3.1 Diagnosis of heart failure (with or without hypertension)

AND

3.2 Ejection fraction is less than or equal to 40 percent

AND

3.3 Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

3.4 ONE of the following:

3.4.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following beta-blockers:

- bisoprolol
- carvedilol
- metoprolol

OR

3.4.2 Patient has a contraindication or intolerance to beta-blocker therapy

AND

3.5 Patient does not have a history of angioedema

AND

3.6 Patient will discontinue any use of concomitant ACE (angiotensin converting enzyme) Inhibitor or ARB (angiotensin II receptor blocker) before initiating treatment with Entresto*

AND

3.7 Patient is not concomitantly on aliskiren therapy

AND

3.8 Entresto is prescribed by, or in consultation with, a cardiologist

Notes	*NOTE: ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto

Product Name: Entresto	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The Entresto dose has been titrated to a dose of 97 mg (milligrams) /103 mg twice daily, or to a maximum dose as tolerated by the patient

AND **2** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-141151
Guideline Name	Entyvio (vedolizumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Entyvio IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	14 Weeks
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Cimzia (certolizumab pegol)
- Humira (adalimumab)
- infliximab

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Entyvio therapy, defined as no more than a 45-day gap in therapy*

AND

5 - Prescribed by or in consultation with a gastroenterologist	
Notes	* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Entyvio IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Entyvio IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	4 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Humira (adalimumab)
- infliximab
- Xeljanz oral tablet (tofacitinib)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Entyvio therapy, defined as no more than a 45-day gap in therapy*

AND

5 - Prescribed by or in consultation with a gastroenterologist

AND

6 - Entyvio IV formulation will be used for induction purposes only and patient will be switched to the Entyvio SC (subcutaneous) formulation for week 6 dose

Product Name: Entyvio IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	N/A - Requests for Entyvio IV should be denied
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for continuing Entyvio IV therapy should be denied. The plan's preferred product is Entyvio SC (SC will require PA)

Notes	Requests for continuing Entyvio IV therapy should be denied. The pla n's preferred product for UC indication is Entyvio SC (SC will require PA)

Product Name: Entyvio SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	14 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

1.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming ONE of the following*:

1.1.2.1 Will be used as a maintenance dose following two doses of Entyvio IV** for induction

OR

1.1.2.2 Patient is currently established on Entyvio IV**

AND

1.1.3 Prescribed by or in consultation with a gastroenterologist

OR

1.2 Patient has received 2 doses of Entyvio IV** for induction

Notes	* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy. ** This product will require prior authorization

Product Name: Entyvio SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

2 . Revision History

Date	Notes
2/29/2024	Updated verbiage/criteria to direct patient to SC formulation

Prior Authorization Guideline

Guideline ID	GL-99453
Guideline Name	Epaned
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Epaned	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is less than 8 years of age

OR

1.2 BOTH of the following:

1.2.1 ONE of the following diagnoses:

- Hypertension
- Heart failure
- Asymptomatic left ventricular dysfunction, defined as left ventricular ejection fraction less than or equal to 35%

AND

1.2.2 ONE of the following:

1.2.2.1 History of failure, contraindication, or intolerance to TWO formulary oral anti-hypertensives (e.g., angiotensin-converting enzyme (ACE) inhibitor, ACE inhibitor combination, angiotensin-receptor blockers (ARB), ARB combination, thiazide diuretic)

OR

1.2.2.2 Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to ONE of the following:

- Oral/motor difficulties
- Dysphagia

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-108666
Guideline Name	Epinephrine Pens
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Epinephrine Pens (Non-Mylan Manufacturer)	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - There is a shortage on Epinephrine Pens manufactured by Mylan.	
Notes	*Only approve other rebatable epinephrine autoinjectors if both the br anded EpiPen and authorized generic are on the FDA shortage list.

Product Name: Epinephrine Pens (Mylan Manufacturer)	
Approval Length	6 month(s)

Guideline Type	Quantity Limit
Approval Criteria **1** - Medication has been used or lost or the member is going on vacation.*	
Notes	Only approve other rebatable epinephrine autoinjectors if both the bra nded EpiPen and authorized generic are on the FDA shortage list

2 . Revision History

Date	Notes
6/23/2022	Updated guideline name as criteria is not specific to only non-mylan products

Prior Authorization Guideline

Guideline ID	GL-99454
Guideline Name	Eplerenone- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Inspra, generic eplerenone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Symptomatic heart failure with reduced ejection fraction (HFrEF) after an acute myocardial infarction

OR

1.2 Hypertension

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-108675
Guideline Name	Epsolay (benzoyl peroxide) cream
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Epsolay	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rosacea

AND

2 - Patient has inflammatory lesions

AND

3 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to one preferred topical product for rosacea (e.g., metronidazole cream/gel/lotion) (verified via paid pharmacy claims)

2 . Revision History

Date	Notes
6/24/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-144656
Guideline Name	Erythropoietic Agents - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Aranesp, Epogen, Procrit, Mircera, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Hematocrit is less than 30% at initiation of therapy

AND

3 - ONE of the following:

3.1 Patient is on dialysis

OR

3.2 ALL of the following:

3.2.1 Patient is NOT on dialysis

AND

3.2.2 The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

4 - If the request is for Aranesp or Mircera; claims history indicates either Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Aranesp, Epogen, Procrit, Mircera, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - ONE of the following:

2.1 Both of the following:

- Patient is on dialysis
- Most recent or average Hct over 3 months is 33% or less (Hgb 11 g/dL or less)

OR

2.2 All of the following:

- Patient is NOT on dialysis
- Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less)
- Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

OR

2.3 Both of the following:

- Request is for a pediatric patient
- Most recent or average Hct over 3 mo is 36% or less (Hgb 12 g/dL or less)

AND

3 - One of the following:

- Decrease in the need for blood transfusion
- Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level

AND

4 - If the request is for Aranesp or Mircera; claims history indicates either Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

2 - Endogenous serum erythropoietin level is less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than 30% at initiation of therapy

Product Name: Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit less than 30% at initiation of therapy

AND

2 - There is a minimum of two additional months of planned chemotherapy

AND

3 - If the request is for Aranesp; claims history indicates either Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Perioperative hematocrit is greater than 30% and less than or equal to 39%

AND

2 - Patient is at high risk for blood loss during surgery

AND

3 - Patient is unable or unwilling to donate autologous blood

AND

4 - Surgery procedure is elective, non-cardiac, and non-vascular

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic disease (MDS)

AND

2 - ONE of the following:

- Serum erythropoietin level less than or equal to 500 milliunits per milliliter
- Hematocrit is less than or equal to 30% at the initiation of therapy

AND

3 - If the request is for Aranesp; claims history indicates either Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Hematocrit remains less than 36%

OR

1.2 Patient has demonstrated a response to therapy

AND

2 - If the request is for Aranesp; claims history indicates either Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C virus (HCV) infection

AND

2 - Patient is receiving ribavirin and interferon therapy

AND

3 - Hematocrit is less than or equal to 30% at initiation of therapy

Product Name: Epogen, Procrit, Retacrit*	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Hematocrit remains less than 36%

OR

1.2 Patient has demonstrated a response to therapy

Notes	*NOTE: Authorization will be issued for 12 months or if patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy.

Product Name: Aranesp, Epogen, Mircera, Procrit, Retacrit*	
Diagnosis	Erythropoietin Stimulating Agents –Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

AND

2 - Requests for coverage in patients with hemoglobin (Hgb) greater than 10 grams per deciliter or hematocrit (Hct) greater than 30% will not be approved

AND

3 - If the request is for Aranesp or Mircera; claims history indicates either Epogen, Procrit, or Retacrit has been tried at maximum doses as indicated by FDA labeling

Notes	*If the request is deemed medically necessary, the authorization will be issued for requested length of therapy.

2 . Revision History

Date	Notes
3/27/2024	Updated embedded steps due to Jan P&T change: Aranesp now Non Preferred (Epogen, Procrit, and Retacrit are the preferred agents)

Prior Authorization Guideline

Guideline ID	GL-116139
Guideline Name	Esbriet, Ofev
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Brand Esbriet, generic pirfenidone, Brand Pirfenidone 534 mg tablets, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by ALL of the following criteria:

1.1 Exclusion of other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by the following:

- ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis)

AND

1.2 ONE of the following:

1.2.1 In patients NOT subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF

AND

2 - The agent is not being used in combination with Esbriet or Ofev

AND

3 - The prescriber is a pulmonologist

AND

4 - If requesting Brand or generic pirfenidone ONLY: patient has tried and failed, or has intolerance to Brand Esbriet

Product Name: Brand Esbriet, generic pirfenidone, Brand Pirfenidone 534 mg tablets, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - The agent is not being used in combination with Esbriet or Ofev

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis (SSc) - associated interstitial lung disease as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)

- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on high-resolution computed tomography (HRCT), involving at least 10 percent of the lungs

AND

2 - The agent is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Chronic fibrosing interstitial lung disease with a progressive phenotype
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype as documented by BOTH of the following criteria:

1.1 Presence of fibrotic ILD as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10 percent of the lungs

AND

1.2 Patient is presenting with clinical signs of progression as defined by ONE of the following in the previous 24 months:

1.2.1 Forced vital capacity (FVC) decline of greater than 10 percent

OR

1.2.2 TWO of the following:

- FVC decline of greater than or equal to 5 percent, but less than 10 percent
- Patient is experiencing worsening respiratory symptoms
- Patient is exhibiting increasing extent of fibrotic changes on chest imaging

AND

2 - The agent is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease, Chronic fibrosing interstitial lung disease with a progressive phenotype
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Ofev is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

2 . Revision History

Date	Notes
10/27/2022	Added pirfenidone as NP target

Prior Authorization Guideline

Guideline ID	GL-99455
Guideline Name	Estrogens- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Femring	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

OR

2 - Diagnosis of moderate to severe vulvar and vaginal atrophy due to menopause

Product Name: Premarin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atrophic vaginitis and kraurosis vulvae

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effecti ve

Prior Authorization Guideline

Guideline ID	GL-117636
Guideline Name	Eucrisa
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Eucrisa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide]

AND

1.2 ONE of the following:

1.2.1 Patient is less than 2 years of age

OR

1.2.2 Patient is greater than or equal to 2 years of age and has history of failure, contraindication, or intolerance to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

2 . Revision History

Date	Notes
12/4/2022	Changed from ST to PA

Prior Authorization Guideline

Guideline ID	GL-124825
Guideline Name	Evkeeza (evinacumab-dgnb)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Evkeeza	
Diagnosis	Homozygous Familial Hypercholesterolemia [HoFH]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 5 years of age or older

AND

2 - Submission of medical records (e.g. chart notes) documenting diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following:

2.1 Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

2.2 Both of the following:

2.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

2.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia in both parents

AND

3 - Submission of medical records (e.g., chart notes) demonstrating that patient has failed to achieve a low-density lipoprotein-cholesterol (LDL-C) goal of less than 100 mg/dL despite use of both of the following: *Paid pharmacy claims may be used to confirm trial requirements

3.1 One of the following:

3.1.1 Patient is currently treated with maximally tolerated statin therapy plus ezetimibe

OR

3.1.2 Patient is unable to tolerate statin therapy as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [B]

- Myalgia (muscle symptoms without CK elevations)

- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

3.1.3 Patient has a labeled contraindication to all statins

OR

3.1.4 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3.2 One of the following:

- Patient has been treated with PCSK9 therapy or did not respond to PCSK9 therapy
- Physician attests that the patient is known to have two LDL-receptor negative alleles (little to no residual function) and therefore would not respond to PCSK9 therapy
- Patient has a history of intolerance or contraindication to PCSK9 therapy
- Patient has previously been treated with Juxtapid (lomitapide)
- Patient has previously been treated with lipoprotein apheresis

AND

4 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

5 - Dose will not exceed 15 milligrams per kilogram of bodyweight infused once every 4 weeks

AND

6 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

Product Name: Evkeeza	
Diagnosis	Homozygous Familial Hypercholesterolemia [HoFH]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting LDL-C reduction from baseline while on Evkeeza therapy

AND

2 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

3 - Dose will not exceed 15 milligrams per kilogram of bodyweight infused once every 4 weeks

AND

4 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

2 . Endnotes

A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. Additionally, in the Evkeeza pivotal trial the primary outcome of change in LDL-C was evaluated at 24 weeks. [1,2,6]
B. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [6]

3 . Revision History

Date	Notes
4/20/2023	New program

Prior Authorization Guideline

Guideline ID	GL-114470
Guideline Name	Evrysdi (risdiplam)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

2.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.2 Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

5 - Patient is not receiving concomitant chronic survival motor neuron (SMN)-modifying therapy [e.g., Spinraza (nusinersen)]

AND

6 - Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

7 - Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include

assessments evaluated prior to receipt of previous chronic SMN-modifying therapy if transitioning therapy)*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

8 - Prescribed by a neurologist with expertise in the treatment of SMA

Notes	*Baseline assessments for patients less than 2 months of age requesting Evrysdi are not necessary in order not to delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status [inclusive of baseline assessments prior to receipt of previous chronic survival motor neuron (SMN)-modifying therapy] as demonstrated by at least ONE of the following exams:

1.1 Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) with ONE of the following:

1.1.1 Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline

OR

1.1.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.2 Hammersmith Infant Neurological Exam Part 2 (HINE-2) with ONE of the following:

1.2.1 Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick

OR

1.2.2 Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

OR

1.2.3 The patient exhibited improvement, or maintenance of previous improvement, in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)

OR

1.2.4 Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

OR

1.3 Hammersmith Functional Motor Scale Expanded (HFMSE) with ONE of the following:

1.3.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.3.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.4 Upper Limb Module (ULM) with ONE of the following:

1.4.1 Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline

OR

1.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.5 Motor Function Measure 32 (MFM-32) with ONE of the following:

1.5.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.5.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

AND

3 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

4 - Patient is not receiving concomitant chronic SMN-modifying therapy [e.g., Spinraza (nusinersen)]

AND

5 - Patient has not previously received gene replacement therapy for the treatment of spinal muscular atrophy (SMA) [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

6 - Prescribed by a neurologist with expertise in the treatment of SMA

2 . Revision History

Date	Notes
9/26/2022	Updated to remove age requirement per FDA expanded indication

Prior Authorization Guideline

Guideline ID	GL-116192
Guideline Name	Exondys - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Exondys	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating Duchenne Muscular Dystrophy

AND

4 - Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

5 - If ambulatory, patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

Product Name: Exondys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has been on therapy for less than 12 months and all of the following:

1.1.1 Patient is tolerating therapy

AND

1.1.2 Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

1.1.3 Prescribed by or in consultation with a neurologist who has experience treating Duchenne Muscular Dystrophy

AND

1.1.4 If ambulatory, patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

OR

1.2 Patient has been on therapy for 12 months or more and all of the following:

1.2.1 Patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients)

AND

1.2.2 Patient is tolerating therapy

AND

1.2.3 Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

1.2.4 Prescribed by or in consultation with a neurologist who has experience treating Duchenne Muscular Dystrophy

AND

1.2.5 If ambulatory, patient's condition has been evaluated via the 6-minute walk test

(6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

2 . Revision History

Date	Notes
10/28/2022	Removed age and ambulatory requirements

Prior Authorization Guideline

Guideline ID	GL-131964
Guideline Name	Ezallor Sprinkle (rosuvastatin)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Ezallor	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is less than 10 years of age

AND

1.1.2 Prescribed by or in consultation with a cardiologist

OR

1.2 Both of the following:

1.2.1 Medication is being used for one of the following:

1.2.1.1 To reduce the risk of one of the following:

- Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
- MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD
- Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD

OR

1.2.1.2 As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in one of the following:

- Adults with primary hyperlipidemia
- Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)

OR

1.2.1.3 As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH)

OR

1.2.1.4 As an adjunct to diet for the treatment of adults with one of the following:

- Primary dysbetalipoproteinemia
- Hypertriglyceridemia

AND

1.2.2 One of the following:

1.2.2.1 Trial and failure, contraindication, or intolerance to generic rosuvastatin tablets (verified via paid pharmacy claims or submitted chart notes)

OR

1.2.2.2 Patient is unable to swallow oral tablets

2 . Revision History

Date	Notes
8/29/2023	New program

Prior Authorization Guideline

Guideline ID	GL-128984
Guideline Name	Fabry Disease Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Fabrazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient is 2 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) confirming ONE of the following:

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

4 - Will not be used in combination with Galafold (migalastat)

Product Name: Elfabrio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Submission of medical records (e.g., chart notes) confirming ONE of the following:

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Will not be used in combination with Galafold (migalastat)

Product Name: Fabrazyme, Elfabrio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
7/26/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99716
Guideline Name	Fasenra
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Fasenra Pen	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80 percent predicted [in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting ONE of the following:

3.1 Asthma is an eosinophilic phenotype as defined by a baseline (pre-benralizumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter within the past 6 weeks

OR

3.2 Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

AND

4 - Fasenra will be used in combination with ONE of the following:

4.1 One high dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

4.2 Combination therapy including BOTH of the following:

4.2.1 One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

4.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

5 - Patient is not receiving Fasenra in combination with one of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

6 - Prescribed by one of the following:

- Pulmonologist
- Allergist

- Immunologist

Product Name: Fasenra Pen	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing controller medication

AND

3 - Patient is not receiving Fasenra in combination with one of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

4 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128980
Guideline Name	Fecal Microbiota Agents
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Rebyota	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Submission of medical records (e.g., chart notes) confirming BOTH of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota*:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

Notes	*Trial requirements may be verified via paid pharmacy claims or submission of medical records/chart notes

Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - Submission of medical records (e.g., chart notes) confirming ALL of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst*:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND **5** - Prescribed by or in consultation with one of the following: • Gastroenterologist • Infectious disease specialist	
Notes	*Trial requirements may be verified via paid pharmacy claims or submission of medical records/chart notes

2 . Endnotes

A. Patients are required to take magnesium citrate 24 hours prior to the first dose of Vowst per the prescribing information. There is currently no efficacy data regarding the use of Vowst without magnesium citrate and the thought is that it helps to clear the antibiotics prior to administration of Vowst. [2,3]

3 . Revision History

Date	Notes
7/26/2023	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99519
Guideline Name	Fentanyl IR
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Fentanyl citrate lozenges (generic Actiq)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

Product Name: Abstral, Brand Actiq, Brand Fentora, generic fentanyl citrate buccal tablet, Lazanda, Subsys

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

AND

5 - History of failure, contraindication, or intolerance to Fentanyl citrate lozenges (generic Actiq) [Document date of trial]

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99458
Guideline Name	Fexmid (cyclobenzaprine 7.5mg)- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Fexmid 7.5mg, generic cyclobenzaprine 7.5mg	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of muscle spasm associated with acute, painful musculoskeletal conditions

AND

2 - Reason or special circumstance the patient cannot use cyclobenzaprine 5 milligram (mg) or 10mg tablet

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-124967
Guideline Name	Filspari (sparsentan)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Filspari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B]

AND

3 - Used to reduce proteinuria

AND

4 - Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.73 m2

AND

5 - Submission of medical records (e.g., chart notes) demonstrating patient has been on a minimum 90-day trial of a maximally tolerated dose of one of the following (paid pharmacy claims may be used to confirm appropriate trial):

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

AND

6 - Medication will not be used in combination with any of the following:

- Angiotensin receptor blockers
- Endothelin receptor antagonists (ERAs) (e.g., ambrisentan, bosentan, Opsumit)
- Aliskiren

AND

7 - Prescribed by or in consultation with a nephrologist

Product Name: Filspari	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a positive clinical response to therapy as demonstrated by a decrease in urine protein-to-creatinine ratio (UPCR) from baseline

AND

2 - Medication is not taken in combination with any of the following:

- Angiotensin receptor blockers
- Endothelin receptor antagonists (ERAs) (e.g., ambrisentan, bosentan, Opsumit)
- Aliskiren

2 . Revision History

Date	Notes
4/24/2023	New program

Prior Authorization Guideline

Guideline ID	GL-116131
Guideline Name	Firdapse
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Firdapse	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine), Ruzurgi (amiframpridine)]

AND

3 - Patient is 6 years of age or older

Product Name: Firdapse	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Firdapse therapy

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine), Ruzurgi (amifampridine)]

2 . Revision History

Date	Notes
10/27/2022	Added age requirement

Prior Authorization Guideline

Guideline ID	GL-99520
Guideline Name	Flucytosine- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Ancobon, generic flucytosine	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of septicemia, endocarditis or a urinary system infection caused by Candida species

OR

1.2 Diagnosis of meningitis or a pulmonary infection caused by Cryptococcus species **AND** **2** - If the patient is being treated for a systemic infection, flucytosine is being used in combination with amphotericin B

Product Name: Brand Ancobon, generic flucytosine*	
Diagnosis	Infectious Diseases Society of America (IDSA) Recommended Regimens
Guideline Type	Prior Authorization
Approval Criteria **1** - The medication is being prescribed by or in consultation with an infectious disease specialist.	
Notes	*Approval duration based on provider recommended treatment duratio ns, up to 12 months.

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-144077
Guideline Name	Forteo, Prolia, Teriparatide, Tymlos - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Preferred Drugs: Brand Forteo, Prolia	
Diagnosis	Patients with osteoporosis at high risk for fracture
Approval Length	12 Months**
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteoporosis

AND

2 - ONE of the following:

2.1 Bone Mineral Density (BMD) T-score less than or equal to -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

OR

2.2 BOTH of the following:

2.2.1 BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.2.2 ONE of the following:

2.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.2.2.2 History of failure, contraindication, or intolerance to ONE conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)**

OR

2.3 ALL of the following:

2.3.1 BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies),

hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.3.2 ONE of the following:

2.3.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.3.2.2 ONE of the following Fracture Risk Assessment Tool (FRAX) 10-year fracture probabilities:

- Major osteoporotic fracture at 20 percent or more
- Hip fracture at 3 percent or more

AND

2.3.3 History of failure, contraindication, or intolerance to ONE conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)*

AND

3 - For Brand Forteo Requests ONLY: Treatment duration has not exceeded a total of 24 months** of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime (APPLIES TO BRAND FORTEO ONLY)

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial **Duration of coverage will be limited to 24 months of cumulative parat hyroid hormone analog therapy (e.g., Forteo, Tymlos) in the patient's l ifetime

Product Name: Non-Preferred Drugs: Brand Teriparatide, generic teriparatide, Tymlos	
Diagnosis	Patients with osteoporosis at high risk for fracture
Approval Length	12 Months**
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteoporosis

AND

2 - ONE of the following:

2.1 Bone Mineral Density (BMD) T-score less than or equal to -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

OR

2.2 BOTH of the following:

2.2.1 BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.2.2 ONE of the following:

2.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.2.2.2 History of failure, contraindication, or intolerance to ALL of the following (Document drug, date, and duration of trial)

- bisphosphonate (e.g. ALENDRONATE, IBANDRONATE)
- selective estrogen receptor modulator (SERM) (e.g RALOXIFENE)
- Prolia (denosumab)
- Brand Forteo (teriparatide)

OR

2.3 ALL of the following:

2.3.1 BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.3.2 ONE of the following:

2.3.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.3.2.2 ONE of the following Fracture Risk Assessment Tool (FRAX) 10-year fracture probabilities:

- Major osteoporotic fracture at 20 percent or more
- Hip fracture at 3 percent or more

AND

2.3.3 History of failure, contraindication, or intolerance to ALL of the following (Document drug, date, and duration of trial)

- bisphosphonate (e.g. ALENDRONATE, IBANDRONATE)
- selective estrogen receptor modulator (SERM) (e.g RALOXIFENE)
- Prolia (denosumab)
- Brand Forteo (teriparatide)

AND

3 - Treatment duration has not exceeded a total of 24 months** of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial **Duration of coverage will be limited to 24 months of cumulative parat hyroid hormone analog therapy (e.g., Forteo, Tymlos) in the patient's l ifetime

Product Name: Preferred Drugs: Brand Forteo, Prolia; Non-Preferred Drugs: Brand Teriparatide, generic teriparatide, Tymlos	
Diagnosis	Patients with osteoporosis at high risk for fracture
Approval Length	12 Months*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Treatment duration has not exceeded a total of 24 months* of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime) NOTE: DOES NOT APPLY TO PROLIA

Notes	*Duration of coverage will be limited to 24 months of cumulative parat hyroid hormone analog therapy (e.g., Forteo, Tymlos) in the patient's l ifetime

2 . Revision History

Date	Notes
3/26/2024	Updated criteria to specify 24 month limit on duration does not apply to Prolia. Added reauth criteria. Changed authorization to Initial auth 12 months, Reauth 12 months

Prior Authorization Guideline

Guideline ID	GL-120434
Guideline Name	Furoscix (furosemide injection)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Furoscix	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of chronic heart failure

AND

2 - Patient has New York Heart Association (NYHA) Class II or III

AND

3 - Patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide)

AND

4 - Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia)

2 . Revision History

Date	Notes
1/24/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99613
Guideline Name	Galafold
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

AND

3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Galafold therapy

AND

2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

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Prior Authorization Guideline

Guideline ID	GL-135435
Guideline Name	Gamifant (emapalumab-lzsg)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Gamifant	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)

AND

2 - Submission of medical records (e.g., chart notes) or paid claims confirming one of the following:

2.1 Disease is one of the following:

- Refractory
- Recurrent
- Progressive

OR

2.2 Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Patient has not received hematopoietic stem cell transplantation (HSCT)

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) demonstrating a positive clinical response to therapy (e.g., improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers)

AND

2 - Patient has not received HSCT

2 . Revision History

Date	Notes
10/27/2023	New program

Prior Authorization Guideline

Guideline ID	GL-135438
Guideline Name	Gattex (teduglutide)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Gattex	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming all of the following:

1.1 Diagnosis of short bowel syndrome

AND

1.2 Patient is 1 year of age and older

AND

1.3 Documentation that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months

AND

2 - Prescribed by or in consultation with a gastroenterologist

Product Name: Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on Gattex therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist [C]

2 . Revision History

Date	Notes
10/27/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99615
Guideline Name	Gaucher's Disease Agents- Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cerdelga	
Diagnosis	Type 1 Gaucher’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher’s disease

AND

2 - Patient is one of the following as detected by a Food and Drug Administration (FDA)-cleared test:

- CYP2D6 extensive metabolizer,
- CYP2D6 intermediate metabolizer
- CYP2D6 poor metabolizer

Product Name: Cerezyme	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher's disease that results in one or more of the following conditions:

- Anemia
- Thrombocytopenia
- Bone disease
- Hepatomegaly or splenomegaly

Product Name: Vpriv, Elelyso	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher's disease

Product Name: Brand Zavesca, generic miglustat	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher's disease

AND

2 - If the request is for generic miglustat, there is a reason or special circumstance why the patient cannot use brand Zavesca

Product Name: Cerdelga, Cerezyme, Elelyso, Vpriv, Brand Zavesca, generic miglustat	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

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Prior Authorization Guideline

Guideline ID	GL-99573
Guideline Name	Generic fluticasone-salmeterol diskus, Wixela Inhub (authorized generic of Advair Diskus), Airduo, fluticasone/salmeterol (authorized generic of Airduo)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Generic fluticasone-salmeterol diskus, Wixela Inhub (authorized generic of Advair Diskus), Airduo, fluticasone/salmeterol (authorized generic of Airduo)	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for Generic fluticasone-salmeterol diskus, Wixela Inhub (authorized generic of Advair Diskus), Airduo, fluticasone/salmeterol (authorized generic of Airduo) should be denied. The plan's preferred products are brand Advair Diskus, Advair HFA, Dulera, Symbicort.	

Prior Authorization Guideline

Guideline ID	GL-144747
Guideline Name	Generic tretinoin cream and gel, generic Avita cream and gel, generic atralin gel
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/21/2024

1 . Criteria

Product Name: generic tretinoin cream and gel, generic Avita cream and gel, generic atralin gel	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for generic tretinoin cream and gel, generic Avita cream and gel, generic atralin gel should be denied. The plan's preferred product is Brand Retin-A cream or gel.*	
Notes	*Brand Retin-A cream or gel may require PA Note: Clinical Program: Brand Over Generic-Not Covered

2 . Revision History

Date	Notes
3/21/2024	Updated guideline to add note that calls out brand is preferred

Prior Authorization Guideline

Guideline ID	GL-99460
Guideline Name	Global Quantity Limits
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review (General)
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review for the treatment of gender dysphoria*
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Notes	* If the above criteria are not met, then refer for clinical review by an appropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Monthly prescription limit review for migraine therapy, benzodiazepines, or muscle relaxants
Approval Length	1 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Notes	*If deemed medically necessary, longer authorization duration is permitted

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Topical products exceeding the allowable package size per fill OR the allowable quantity per month
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The physician attests that a larger quantity is needed for treatment of a larger surface area.

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

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Prior Authorization Guideline

Guideline ID	GL-139361
Guideline Name	GLP-1 Agonists - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Preferred Drugs: Bydureon, Byetta, Trulicity, Victoza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Submission of medical records (e.g. chart notes, lab work, imaging) confirming both of the following:

- Diagnosis of type 2 diabetes mellitus
- Baseline A1C greater than or equal to 6.5%

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - Patient is 10 years of age or older

AND

3 - Drug is not solely being used for weight loss

Product Name: Non-Preferred Drugs: Adlyxin, Bydureon BCise, Mounjaro, Ozempic	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Submission of medical records (e.g. chart notes, lab work, imaging) confirming both of the following:

- Diagnosis of type 2 diabetes mellitus
- Baseline A1C greater than or equal to 6.5%

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - History of a 90 day trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- Byetta
- Victoza
- Trulicity

AND

3 - One of the following:

- For Bydureon BC ONLY: Patient is 10 years of age or older
- For Adlyxin, Mounjaro, Ozempic ONLY: Patient is 18 years of age or older

AND

4 - Drug is not solely being used for weight loss

Product Name: Non-Preferred: Rybelsus	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Submission of medical records (e.g. chart notes, lab work, imaging) confirming both of the following:

- Diagnosis of type 2 diabetes mellitus
- Baseline A1C greater than or equal to 6.5%

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 History of a 90 day trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- Byetta
- Victoza
- Trulicity

OR

2.2 BOTH of the following:

2.2.1 The patient is unable to self-inject due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

2.2.2 History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana
- Invokamet
- Synjardy

- Xigduo XR

AND

3 - Patient is 18 years of age or older

AND

4 - Drug is not solely being used for weight loss

2 . Revision History

Date	Notes
1/23/2024	Added criteria for A1C. Updated submission of records verbiage (clinical intent the same).

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Prior Authorization Guideline

Guideline ID	GL-108674
Guideline Name	Glycopyrrolate Products
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Cuvposa oral solution, Dartisla ODT, Brand Robinul, Brand Robinul Forte	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to generic glycopyrrolate tablets or oral solution (verified via pharmacy paid claims or submission of medical records/chart notes)

Product Name: Glycopyrrolate injection 0.6mg/3ml	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to preferred glycopyrrolate injection strengths (e.g., 0.2 mg/ml, 0.4mg/2ml, 1 mg/5ml, 4mg/20ml) (verified via pharmacy paid claims or submission of medical records/chart notes)

2 . Revision History

Date	Notes
6/24/2022	Added NP glycopyrrolate inj as target. Changed guideline name to Gl ycopyrrolate Products.

Prior Authorization Guideline

Guideline ID	GL-125568
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: leuprolide acetate inj kit 5 mg/mL, Lupron Depot Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)

AND

2 - Onset of secondary sexual characteristics in one of the following:

2.1 Females less than or equal to 8 years of age

OR

2.2 Males less than or equal to 9 years of age

AND

3 - Confirmation of diagnosis as defined by one of the following:

3.1 Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)

OR

3.2 A pubertal luteinizing hormone response to a gonadotropin releasing hormone (GnRH) stimulation test

OR

3.3 Bone age advanced one year beyond the chronological age

AND

4 - If the request is for Triptodur or Fensolvi, history of failure, contraindication, or intolerance to Lupron-Depot Ped

Product Name: leuprolide acetate inj kit 5 mg/mL, Lupron Depot Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving therapy for central precocious puberty

AND

2 - Documentation of positive clinical response to therapy

AND

3 - Patient is ONE of the following (younger than the appropriate time point for the onset of puberty):

3.1 Female younger than 11 years of age

OR

3.2 Male younger than 12 years of age

Product Name: Lupaneta Pack, Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to both of the following:

2.1.1 Oral contraceptives or depot medroxyprogesterone (e.g., Depo- Provera)

AND

2.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)

OR

2.2 Patient has had surgical ablation to prevent recurrence

AND

3 - If the request is for Lupaneta Pack, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupaneta Pack, Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - Recurrence of symptoms following an initial course of therapy

AND

3 - Concurrently to be used with add-back therapy (e.g., progestin, estrogen, or bone sparing agents)

Product Name: Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Uterine Leiomyomata (Fibroids)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 For the treatment of uterine leiomyomata-related anemia

AND

1.1.2 Patient did not respond to iron therapy of 1 month duration

AND

1.1.3 For use prior to surgery

OR

1.2 For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Gender dysphoria in adolescents
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

2 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

3 - Patient has experienced puberty development to at least Tanner stage 2

AND

4 - One of the following laboratory tests, based upon the laboratory reference range, confirming:

- Pubertal levels of estradiol in females
- Pubertal levels of testosterone in males
- Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
- A pubertal luteinizing hormone response to a gonadotropin-releasing hormone (GnRH) stimulation test

AND

5 - A letter from the prescriber and/or formal documentation stating all of the following:

5.1 Patient has experienced pubertal changes that have resulted in an increase of their gender dysphoria that has significantly impaired psychological or social functioning

AND

5.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

5.3 Both of the following:

5.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

5.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

5.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

AND

6 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Gender dysphoria in adolescents
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Documentation (within the last 6 months) of appropriate luteinizing hormone (LH) suppression
- Change in dosing

AND

2 - Documented diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

3 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

4 - A letter from the prescriber and/or formal documentation stating all of the following:

4.1 Patient continues to meet their individual goals of therapy for gender dysphoria

AND

4.2 Patient continues to have a strong affinity for the desired (opposite of natal) gender

AND

4.3 Discontinuation of treatment and subsequent pubertal development would interfere with or impair psychological functioning and well-being

AND

4.4 Coexisting psychiatric and medical comorbidities or social problems that may interfere with treatment continue to be addressed or removed

AND

4.5 Both of the following:

4.5.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

4.5.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

4.6 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

2 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

3 - Gonads (i.e., testes, ovaries) have not been removed and are functional (e.g., hormone producing)

AND

4 - Patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

5 - Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

6 - A letter from the prescriber and/or formal documentation stating all of the following:

6.1 Transgender patient has identified goals of gender-affirming hormone therapy

AND

6.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

6.3 Both of the following:

6.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

6.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

6.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

AND

7 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Documentation (within the last 6 months) of appropriate luteinizing hormone (LH) suppression
- Change in dosing

AND

2 - Documented diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

3 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

4 - Gonads (i.e., testes, ovaries) are intact

AND

5 - Patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

6 - Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

7 - A letter from the prescriber and/or formal documentation stating all of the following:

7.1 Transgender patient continues to meet goals of gender-affirming hormone therapy

AND

7.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment continue to be addressed or removed

AND

7.3 Both of the following:

7.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

7.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

7.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in pre-menopausal women

AND

2 - Patient is receiving a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

AND

3 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot.

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate inj kit 5 mg/mL, Triptodur, Fensolvi, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving gonadotropin-releasing hormone (GnRH) analog therapy for the purpose of fertility preservation

AND

2 - Patient continues to receive a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

Product Name: Lupron Depot 7.5 mg, 22.5 mg, 30 mg and 45 mg, leuprolide acetate inj kit 5 mg/mL, Leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Advanced or Metastatic Prostate Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

2 . Revision History

Date	Notes
5/25/2023	Added new GPI for Lupron Depot Ped

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Prior Authorization Guideline

Guideline ID	GL-141352
Guideline Name	Gralise, Horizant - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Brand Gralise, generic gabapentin (once-daily)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postherpetic neuralgia (PHN)

AND

2 - Trial and failure or intolerance to generic immediate-release gabapentin (generic for Neurontin)

AND

3 - For generic gabapentin (once-daily) requests ONLY: Trial and failure or intolerance to Brand Gralise

Product Name: Horizant	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of postherpetic neuralgia (PHN)
- Trial and failure or intolerance to generic immediate-release gabapentin (generic for Neurontin)

OR

1.2 Diagnosis of restless legs syndrome

2 . Revision History

Date	Notes
2/28/2024	Added new GPIs for generic Gralise with step through Brand Gralise (preferred). Specified trial of preferred generic gabapentin is "immedi ate-release, generic for Neurontin". Added step through preferred IR gabapentin for Horizant PHN indication.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136591
Guideline Name	Growth Hormone, Growth Stimulating Agents - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/21/2023

1 . Criteria

Product Name: All products	
Diagnosis	Idiopathic Short Stature (ISS)
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for coverage for diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved	
Notes	Approval Length: N/A - Requests for Idiopathic Short Stature (ISS) sh ould not be approved. Deny as a benefit exclusion.

Product Name: Non Preferred* Humatrope, Ngenla, Nutropin AQ NuSpin, Saizen, Saizen Click Easy, Serostim, Skytrofa, Sogroya, Zorbitive*	
Approval Length	N/A - Requests for Non-Preferred Drugs should not be approved
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed ALL preferred products listed below:

- Brand Genotropin/Genotropin Miniquick
- Brand Norditropin Flexpro
- Brand Omnitrope
- Brand Zomacton

Notes	*Requests for coverage of Non-Preferred drugs are not authorized and will not be approved. Patient must use one of the preferred products listed above. All Non preferred products will be denied for appeals process.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following:

1.1.1 All of the following:

- Infant is less than 4 months of age
- Infant has growth deficiency
- Prescribed by an endocrinologist

OR

1.1.2 BOTH of the following:

- History of neonatal hypoglycemia associated with pituitary disease
- Prescribed by an endocrinologist

OR

1.1.3 BOTH of the following:

- Diagnosis of panhypopituitarism
- Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of pediatric growth hormone (GH) deficiency as confirmed by ONE of the following:

1.2.1.1 Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is greater than 2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height

OR

1.2.1.2 Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

OR

1.2.1.3 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.4 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 ONE of the following:

1.2.2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.2.3.1 BOTH of the following:

1.2.3.1.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa
- Growth hormone releasing hormone

AND

1.2.3.1.2 BOTH GH response values are less than 10 micrograms per liter

OR

1.2.3.2 BOTH of the following:

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 ONE of the following is below the age and gender adjusted normal range as provided by the physician's lab:

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

1.2.4 ONE of the following:

1.2.4.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

1.2.4.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

1.2.5 Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:**

- Previous height and date obtained
- Current height and date obtained

AND

2 - BOTH of the following:**

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

AND

3 - Calculated height (growth) velocity over the past 12 months

AND

4 - ONE of the following:

4.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

4.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

5 - ONE of the following:

5.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

5.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

6 - Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency. ** Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome

AND

2 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 BOTH of the following:

1.1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

AND

1.1.2 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

1.2.3 Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small for gestational age (SGA) based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by documentation that ONE of the following is below the third percentile for gestational age (more than 2 standard deviations [SD] below population mean):

- Birth weight
- Birth length

AND

2 - Documentation that height remains less than or equal to the third percentile (more than 2 SD below population mean)

AND

3 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)

Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with ONE of the following:

1.1 BOTH of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 BOTH of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 ONE of the following:

1.2.2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the fifth percentile on growth charts for age and gender

AND

3 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult growth hormone deficiency (GHD) as a result of ONE of the following:

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 BOTH of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has undergone ONE of the following GH (growth hormone) stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- Glucagon
- ARG

AND

2.1.2 ONE of the following peak GH values:

2.1.2.1 ITT less than or equal to 5 micrograms per liter

OR

2.1.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

2.1.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

2.1.2.4 ARG less than or equal to 0.4 micrograms per liter

OR

2.2 BOTH of the following:

2.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting deficiency of THREE of the following anterior pituitary hormones:

- Prolactin
- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

2.2.2 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - ONE of the following:

3.1 Diagnosis of panhypopituitarism

OR

3.2 Other diagnosis and not used in combination with BOTH of the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole),Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

4 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

5 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of Insulin-like Growth Factor 1 (IGF-1)/Somatomedin C level within the past 12 months

AND

2 - ONE of the following:

2.1 Diagnosis of panhypopituitarism

OR

2.2 Other diagnosis and not used in combination with BOTH of the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

3 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

4 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

2 - Documentation of ONE of the following:

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

3.1 BOTH of the following:

3.1.1 Documentation of high risk of growth hormone (GH) deficiency due to GH deficiency in childhood from ONE of the following:

3.1.1.1 Embryopathic/congenital defects

OR

3.1.1.2 Genetic mutations

OR

3.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

3.1.1.4 Panhypopituitarism

OR

3.1.1.5 Deficiency of THREE of the following anterior pituitary hormones:

- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- Prolactin
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

3.1.2 ONE of the following:

3.1.2.1 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

3.1.2.2 ALL of the following:

3.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

3.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

3.1.2.2.3 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- ARG
- Glucagon

AND

3.1.2.2.4 ONE of the following peak GH values:

3.1.2.2.4.1 ITT less than or equal to 5 micrograms per liter

OR

3.1.2.2.4.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared

- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

3.1.2.2.4.3 Glucagon less than or equal to 3 micrograms per liter

OR

3.1.2.2.4.4 ARG less than or equal to 0.4 micrograms per liter

OR

3.2 ALL of the following:

3.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

3.2.2 Discontinued GH therapy for at least 1 month

AND

3.2.3 BOTH of the following:

3.2.3.1 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- GHRH and ARG
- ARG
- Glucagon

AND

3.2.3.2 ONE of the following peak GH values:

3.2.3.2.1 ITT less than or equal to 5 micrograms per liter

OR

3.2.3.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

3.2.3.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

3.2.3.2.4 ARG less than or equal to 0.4 micrograms per liter

AND

4 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro, Brand Omnitrope, Brand Zomacton)	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 [Insulin-like Growth Factor 1] and IGFBP-3 [Insulin-like growth factor binding protein 3] levels)

AND

2 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

3 - Prescribed by an endocrinologist

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV)-associated wasting syndrome or cachexia

AND

2 - Documentation of ONE of the following:

2.1 Unintentional weight loss of greater than 10 percent over the last 12 months

OR

2.2 Unintentional weight loss of greater than 7.5 percent over the last 6 months

OR

2.3 Loss of 5 percent body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) less than 20 kilograms per meter squared

OR

2.5 ONE of the following:

2.5.1 ALL of the following:

- Patient is male
- BCM less than 35 percent of total body weight
- BMI less than 27 kilograms per meter squared

OR

2.5.2 ALL of the following:

- Patient is female
- BCM less than 23 percent of total body weight
- BMI less than 27 kilograms per meter squared

AND

3 - A nutritional evaluation has been completed since onset of wasting first occurred

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes)

AND

5 - Patient's anti-retroviral therapy has been optimized to decrease the viral load

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (i.e., greater than or equal to 2 percent increase in body weight and/or body cell mass [BCM])

AND

2 - ONE of the following targets or goals has not been achieved:

- Weight
- BCM
- Body Mass Index (BMI)

Product Name: Zorbtive*	
Diagnosis	Short Bowel Syndrome
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements)

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive*

Notes	*Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied.

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 Documentation of ALL of the following:

1.1.1 Diagnosis of severe primary Insulin-like Growth Factor 1 (IGF-1) deficiency

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone levels

AND

1.1.5 Documentation of open epiphyses on last bone radiograph

AND

1.1.6 The patient will not be treated with concurrent growth hormone therapy

AND

1.1.7 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

1.2.2 Documentation of open epiphyses on last bone radiograph

AND

1.2.3 The patient will not be treated with concurrent growth hormone therapy

AND

1.2.4 Prescribed by an endocrinologist

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not obtained
- Expected adult height goal

AND

3 - Patient is not treated with concurrent growth hormone therapy

AND **4** - Prescribed by an endocrinologist	
Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

2 . Revision History

Date	Notes
11/20/2023	Moved Omnitrope and Zomacton to preferred due to drug shortages, updated criteria to reflect changes.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99463
Guideline Name	HCG
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Novarel, Ovidrel, Brand Pregnyl, generic chorionic gonadotropin	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-99464
Guideline Name	Hemangeol
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Hemangeol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of proliferating infantile hemangioma

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use generic propranolol oral solution

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144633
Guideline Name	Hemophilia Clotting Factors
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Corifact	
Diagnosis	Congenital Factor XIII Deficiency (i.e., Fibrin Stabilizing Factor Deficiency)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital factor XIII deficiency

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Tretten	
Diagnosis	Congenital Factor XIII Deficiency (i.e., Fibrin Stabilizing Factor Deficiency)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital factor XIII A-subunit deficiency

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Humate-P	
Diagnosis	Von Willebrand Disease (VWD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of severe von Willebrand disease

OR

1.2 BOTH of the following:

- Diagnosis of mild or moderate von Willebrand disease
- History of failure, contraindication or intolerance to treatment with desmopressin

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding

Product Name: Alphanate	
Diagnosis	Von Willebrand Disease (VWD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild or moderate von Willebrand disease

AND

2 - Used for peri-operative management of surgical bleeding

AND

3 - History of failure, contraindication or intolerance to treatment with desmopressin

Product Name: Wilate or Vonvendi	
Diagnosis	Von Willebrand Disease (VWD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of von Willebrand disease

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding
- Routine prophylactic treatment

Product Name: NovoSeven RT	
Diagnosis	Congenital Factor VII Deficiency
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital factor VII deficiency

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Routine prophylactic treatment of bleeding

Product Name: Advate, Alphanate, Humate-P, Hemofil M, KoAte, KoAte-DVI, Kogenate FS, Kovaltry, NovoEight, Nuwiq, Recombinate, Xyntha, or Xyntha Solofuse	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Eloctate	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

4 - ONE of the following:

4.1 BOTH of the following:

- Dose does not exceed 50 IU/kg
- Infusing no more frequently than every 4 days

OR

4.2 Requested dosage regimen does not exceed 12.5 IU/kg/day

OR

4.3 BOTH of the following:

4.3.1 Patient is less than 6 years of age

AND

4.3.2 ONE of the following:

- Pharmacokinetic (PK) testing results suggest that dosing more intensive than 50 IU/kg is required
- PK testing results suggest that dosing more frequently than every 3 to 5 days is required
- PK testing results suggest that dosing more intensive than 14.5 IU/kg/day is required

Product Name: Jivi

Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Peri-operative management of surgical bleeding
- Routine prophylactic treatment of bleeding
- Treatment of bleeding episodes

AND

3 - Patient has previously received Factor VIII replacement therapy

AND

4 - Patient is 12 years of age or older

AND

5 - Patient is not a candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

6 - Patient is not to receive routine infusions more than 2 times per week

Product Name: Afstyla	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate] as attested by the prescribing physician

AND

4 - ONE of the following:

4.1 Patient is not to receive routine infusions more frequently than 3 times per week

OR

4.2 BOTH of the following:

- Patient is less than 12 years of age
- Pharmacokinetic (PK) testing results suggest that more frequently than 3 times per week dosing is required

Product Name: Hemlibra	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of severe hemophilia A

AND

1.1.2 Documentation of endogenous factor VIII level less than 1% of normal factor VIII (< 0.01 IU/mL)

AND

1.1.3 Physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes

OR

1.2 All of the following:

1.2.1 One of the following:

1.2.1.1 BOTH of the following:

- Diagnosis of moderate hemophilia A
- Documentation of endogenous factor VIII level greater than or equal to 1% to less than 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

OR

1.2.1.2 Both of the following:

- Diagnosis of mild hemophilia A
- Documentation of endogenous factor VIII level greater than or equal to 5% (greater than 0.05 IU/mL)

AND

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

AND

1.2.3 Physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes

OR

1.3 BOTH of the following:

- Diagnosis of hemophilia A
- Patient has developed high-titer factor VIII inhibitors (greater than or equal to 5 Bethesda units [BU])

AND

2 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name: FEIBA	
Diagnosis	Hemophilia A
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - One of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: NovoSeven RT, Obizur	
Diagnosis	Acquired factor VIII Hemophilia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired factor VIII hemophilia (e.g., acquired hemophilia A, Factor VIII deficiency)

AND

2 - Treatment or prevention of bleeding episodes

Product Name: Adynovate

Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - One of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

4 - One of the following:

4.1 BOTH of the following:

- Patient is not to receive routine infusions more frequently than 2 times per week
- Patient is not to receive a routine dose greater than 50 IU/kg

OR

4.2 ALL of the following:

- Patient is less than 12 years of age
- Patient is not to receive routine infusions more frequently than 2 times per week

- Patient is not to receive a routine dose greater than 70 IU/kg

Product Name: Esperoct	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

AND

3 - ONE of the following:

3.1 Patient is not to receive routine infusions more frequently than 2 times per week

OR

3.2 BOTH of the following:

- Patient is less than 12 years of age
- Pharmacokinetic (PK) testing results suggest that more frequent than 2 times per week dosing is required

Product Name: Wilate

Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

2.1 Routine prophylactic treatment of bleeding

OR

2.2 Treatment of bleeding episodes

Product Name: NovoSeven RT	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - One of the following:

- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Altuviiio	
Diagnosis	Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Prevention of bleeding in surgical interventions or invasive procedures (e.g., surgical prophylaxis)
- Prevention of bleeding episodes (i.e., routine prophylaxis)

AND

3 - Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician

AND

4 - Both of the following:

- Dose does not exceed 50 IU/kg

- Patient is infusing no more frequently than every 7 days

Product Name: AlphaNine SD, Mononine, Profilnine, Profilnine SD	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - One of the following:

- Routine prophylactic treatment
- Treatment of bleeding episodes

Product Name: BeneFIX, Rixubis, Alprolix, Idelvion, Ixinity, or Rebinyn	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - ONE of the following:

- Routine prophylactic treatment
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: FEIBA	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - ONE of the following:

- Routine prophylactic treatment of bleeding
- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: NovoSeven RT	
Diagnosis	Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia B

AND

2 - Documentation of inhibitors (e.g., Bethesda inhibitor assay)

AND

3 - ONE of the following:

- Peri-operative management of surgical bleeding
- Treatment of bleeding episodes

Product Name: Fibryga, RiaSTAP	
Diagnosis	Fibrinogen Deficiency (i.e., Factor I deficiency)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia

AND

2 - Treatment of bleeding episodes

Product Name: NovoSeven RT	
Diagnosis	Glanzmann Thrombasthenia

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Glanzmann's thrombasthenia

AND

2 - Refractory to platelet transfusions

AND

3 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding

Product Name: Coagadex	
Diagnosis	Congenital Factor X Deficiency
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital Factor X deficiency

AND

2 - ONE of the following:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding

- Routine prophylactic treatment

2 . Background

Benefit/Coverage/Program Information

Background:

Advate, Xyntha, Xyntha Solofuse, Alphanate, Humate-P, Hemofil M, Koate, Koate-DVI, Kogenate FS, Kovaltry, NovoEight, Recombinate, Nuwiq, Eloctate, Jivi, Afstyla, Hemlibra, Adynovate, Esperoct, Altuviiio, and FEIBA and are indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

- Control and prevention of bleeding episodes
- Peri-operative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Wilate is indicated in adolescents and adults with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding episodes.

NovoSeven RT is indicated for the treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. It is also indicated in the treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia.

Corifact is indicated for routine prophylactic treatment and peri-operative management of surgical bleeding in adult and pediatric patients with congenital factor XIII deficiency.

Tretten is indicated for routine prophylaxis for bleeding with congenital factor XIII A-subunit deficiency.

Alphanate, Humate-P, Wilate, Vonvendi are indicated for von Willebrand disease for:

- Treatment of bleeding episodes
- Peri-operative management of surgical bleeding
- Routine prophylactic treatment (Wilate and Vonvendi only)

Obizur is indicated for acquired factor VIII hemophilia (e.g., acquired hemophilia A, Factor VIII deficiency).

AlphaNine SD, Mononine, Profilnine/SD, BeneFIX, Rixubis, Ixinity, Alprolix, Idelvion, Rebinyn, FEIBA and NovoSeven RT are indicated for Hemophilia B.

Fibryga and RiaSTAP are indicated for congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Coagadex is indicated for congenital Factor X deficiency.

Table 1: Brand/generic designations of blood clotting products.

Product	Brand Name
Factor VIIa (recombinant)	NovoSeven® RT [coagulation factor VIIa (recombinant)] Sevenfact™ [coagulation factor VIIa (recombinant)-jncw]
Factor XIII (plasma-derived)	Corifact® [factor XIII concentrate (human)]
Factor VIII (plasma-derived)	Hemofil M® [antihemophilic factor (human)]
	Koate®-DVI [antihemophilic factor (human)]
Factor VIII (plasma-derived) / von Willebrand Factor Complex (plasma-derived)	Alphanate® [antihemophilic factor (human)]
	Humate-P® [antihemophilic factor (human)]
	Wilate® [antihemophilic factor (human)]
Factor VIII (recombinant)	Advate® [antihemophilic factor (recombinant)]
	Helixate® FS [antihemophilic factor (recombinant)]
	Kogenate® FS [antihemophilic factor (recombinant)]
	Kovaltry® [antihemophilic factor (recombinant)]

	Novoeight® [antihemophilic factor (recombinant)]
	Nuwiq® [antihemophilic factor (recombinant)]
	Recombinate® [antihemophilic factor (recombinant)]
	Xyntha® [antihemophilic factor (recombinant)]
	Xyntha® Solofuse™ [antihemophilic factor (recombinant)]
Factor IX (plasma-derived)	AlphaNine® SD [coagulation factor IX (human)]
	Mononine® [coagulation factor IX (human)]
	Profilnine SD® [factor IX complex human)]
Factor IX (recombinant)	BeneFIX® [coagulation factor IX (recombinant)]
	Ixinity® [coagulation factor IX (recombinant)]
	Rixubis® [coagulation factor IX (recombinant)]
Factor IX (recombinant), long-acting	Alprolix® [coagulation factor IX (recombinant), Fc fusion protein]
	Idelvion® [coagulation factor IX (recombinant), albumin fusion protein]
	Rebinyn® [coagulation factor IX (recombinant), GlycoPEGylated]
Anti-Inhibitor Coagulant Complex (plasma-derived)	FEIBA® [anti-inhibitor coagulant complex (human)]
Fibrinogen Concentrate (plasma-derived)	RiaSTAP® [fibrinogen concentrate (human)]
	Fibryga® [fibrinogen (human)]
Factor XIII A-subunit (recombinant)	Tretten® [coagulation factor XIII A-subunit (recombinant)]
Factor VIII (recombinant), long-acting	Adynovate® [antihemophilic factor (recombinant), PEGylated]
	Afstyla® [antihemophilic factor (recombinant)]
	Altuviiio [antihemophilic factor (recombinant)]
	Eloctate® [antihemophilic factor (recombinant), Fc fusion protein]
	Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei]
	Jivi® [antihemophilic factor (recombinant), PEGylated-aucl]
Factor VIII (recombinant), porcine sequence	Obizur® [antihemophilic factor (recombinant), porcine sequence]
Factor X (plasma-derived)	Coagadex® [coagulation factor X (human)]
Von Willebrand Factor (recombinant)	Vonvendi® [von Willebrand factor (recombinant)]

Bispecific factor IXa- and factor X-directed antibody	Hemlibra® (emicizumab-kxwh)

3 . Revision History

Date	Notes
3/19/2024	Added new GPI for Hemlibra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125214
Guideline Name	Hepatitis C - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Preferred: sofosbuvir-velpatasvir (authorized generic of Epclusa)**, Mavyret**	
Diagnosis	Hepatitis C Retreatment
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic Hepatitis C infection status which has been confirmed by detectable serum hepatitis C virus (HCV) RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request

AND

2 - Age of the patient is Food and Drug Administration (FDA) approved for the specific HCV DAA (Direct Acting Antiviral) product

AND

3 - The prescribing provider assesses the patient's ability to adhere to the HCV DAA treatment plan and attests the assessment has been documented within the clinical record. For patients that would benefit from adherence aids, the treating provider shall refer the patient to a treatment adherence program

AND

4 - Patient agrees to adhere to the proposed course of treatment, including taking medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program

AND

5 - One of the following:

5.1 Patient has been screened for Hepatitis A and B and has received one Hepatitis A and one Hepatitis B vaccine prior to requesting treatment

OR

5.2 Patient demonstrates laboratory evidence of immunity to Hepatitis A and B

AND

6 - The Prescriber must submit the following information with the request for HCV DAA medications to be considered:

6.1 HCV treatment history and responses to treatment

AND

6.2 Current medication list

AND

6.3 Laboratory results for all of the following:

- HCV screen test results
- Genotype and current baseline HCV viral load
- Total bilirubin
- Albumin level
- International Normalized Ratio (INR)
- Creatinine Clearance (CrCl) or Glomerular Filtration Rate (GFR)
- Liver Function Tests (LFTs)
- Complete Blood Count (CBC)
- Viral resistance status (when applicable)
- Hepatic status (Child Pugh Score)

AND

7 - If the HCV DAA product is being used in combination with ribavirin, the prescribing provider attests to monitoring hemoglobin levels periodically

AND

8 - The prescribing provider attests to monitoring HCV RNA levels obtained at 12- and 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR)

AND

9 - DAA HCV treatment coverage is NOT provided for ANY of the following:

9.1 DAA dosages greater than the FDA approved maximum dosage

OR

9.2 Patients whose comorbidities are such that their life expectancy is one year or less

OR

9.3 Patients currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)

OR

9.4 Lost or stolen medication absent of good cause

OR

9.5 Fraud, waste, or misuse of HCV DAA medications

Notes	*Approval length: Mavyret = 8 Week(s), sofosbuvir-velpatasvir (authorized generic of Epclusa) = 12 Weeks(s). **Preferred drugs Mavyret and sofosbuvir-velpatasvir (authorized generic of Epclusa) will be approved without requiring prior authorization ONE time per lifetime. Requests for retreatment or non-preferred drugs will require PA. Refer to AASLD for specific approval durations AASLD: https://www.hcvguidelines.org/contents

Product Name: Non-Preferred: Brand Epclusa, Brand Harvoni, ledipasvir-sofosbuvir (authorized generic of Harvoni), Sovaldi, Zepatier	
Diagnosis	Hepatitis C
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient was adherent to previous DAA therapy as evidenced by submission of medical records and/or pharmacy prescription claims

OR

1.2 If prior therapy was discontinued due to adverse effects from the DAA, the medical

record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider

AND

2 - The patient's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record

AND

3 - Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when BOTH of the following are true

- Required for regimens whereby the FDA (Food and Drug Administration) requires such testing prior to treatment to ensure clinical appropriateness
- Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen

AND

4 - HCV retreatment with a DAA shall NOT be approved for ANY of the following:

4.1 The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy

OR

4.2 Is considered an experimental service

OR

4.3 Monotherapy of Sofosbuvir (Sovaldi)

OR

4.4 DAA dosages greater than the FDA approved maximum dosage

OR

4.5 Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request

OR

4.6 Patients whose comorbidities are such that their life expectancy is one year or less

OR

4.7 Patients currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)

OR

4.8 Lost or stolen medication absent of good cause

OR

4.9 Fraudulent use of HCV DAA medications

AND

5 - If the request if for brand Epclusa or brand Harvoni BOTH of the following:

5.1 The patient has a therapeutic failure, contraindication, or intolerance to the generic as evidenced by submission of medical records or claims history

AND

5.2 The prescriber must submit the FDA MedWatch form

Notes	*NOTE: The approval length should be as recommended per AASLD. Refer to AASLD for specific approval durations. AASLD: https://www.hcvguidelines.org/contents

Product Name: Non-Preferred: Brand Harvoni, ledipasvir-sofosbuvir (authorized generic of Harvoni)	
Diagnosis	Hepatitis C Retreatment
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

Product Name: Non-Preferred: Vosevi, Viekira Pak	
Diagnosis	Hepatitis C
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - One of the following:

2.1 Patient is a previous relapser to an NS5A-based regimen (e.g., Daklinza [daclatasvir]; Epclusa [sofosbuvir/velpatasvir]; Harvoni [ledipasvir/sofosbuvir]; Mavyret [glecaprevir/pibrentasvir]; Technivie [ombitasvir/paritaprevir/ritonavir]; Viekira [ombitasvir/paritaprevir/ritonavir & dasabuvir]; Zepatier [elbasvir/grazoprevir])

OR

2.2 Patient is a previous relapser to a sofosbuvir-based regimen without an NS5A inhibitor

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Non-Preferred: Vosevi, Viekira Pak	
Diagnosis	Hepatitis C: Prior Failure to Vosevi/Viekira Pak

Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Both of the following:

2.1 Patient had a prior treatment failure with Vosevi or Viekira

AND

2.2 Used in combination with ribavirin

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Pegasys, PegIntron	
Diagnosis	Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

3 - Will be used as part of a combination antiviral treatment regimen

Product Name: Ribavirin tablets and capsules	
Diagnosis	Hepatitis C
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Used in combination with a direct-acting agent

2 . Revision History

Date	Notes
5/2/2023	Specified Preferred Agents criteria is for Retreatment in the diagnosis section. No changes to clinical criteria.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137604
Guideline Name	Hereditary Angioedema (HAE) Agents - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Cinryze, Haegarda, Orladeyo or Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of hereditary angioedema (HAE) confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal

- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - For prophylaxis against HAE attacks

AND

3 - One of the following:

- Patient is 2 years of age or older (Applies to Takhzyro only)
- Patient is 6 years of age or older (applies to Cinryze and Haegarda only)
- Patient is 12 years of age or older (Applies to Orladeyo only)

AND

4 - Prescribed by or in consultation with one of the following:

- Immunologist
- Allergist

AND

5 - ONE of the following: (APPLIES TO CINRYZE, ORLADEYO, AND TAKHZYRO ONLY):

5.1 Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda

OR

5.2 Submission of medical records documenting patient is currently on Cinryze, Orladeyo, or Takhzyro therapy

Notes	*Please note: Preferred agent is Haegarda

Product Name: Berinert, Cinryze [off-label], Brand Firazyr, Generic icatibant, Kalbitor, Ruconest, or Sajazir	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of hereditary angioedema (HAE) confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - For the treatment of acute HAE attacks

AND

3 - Not used in combination with other approved treatments for acute HAE attacks

AND

4 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze only)
- Patient is 12 years of age or older (applies to Kalbitor)
- Patient is 18 years of age or older (applies to Brand Firazyr, generic icatibant, and Sajazir only)

AND

5 - Prescribed by or in consultation with one of the following:

- Immunologist
- Allergist

AND

6 - ONE of the following (APPLIES TO CINRYZE, BRAND FIRAZYR, KALBITOR, RUCONEST, AND SAJAZIR ONLY):

6.1 Submission of medical records documenting a history of failure, contraindication, or intolerance to BOTH of the following preferred HAE agents:

- Berinert
- generic icatibant

OR

6.2 Submission of medical records or paid claims documenting patient is currently on Cinryze, Brand Firazyr, Kalbitor, Ruconest, or Sajazir therapy

Notes	Please note: Preferred HAE agents are Berinert and generic icatibant

2 . Revision History

Date	Notes
12/11/2023	Updates from Oct P&T to reflect Preferred agents are now Haegarda , Berinert, and generic icatibant.

Prior Authorization Guideline

Guideline ID	GL-116931
Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/17/2022

1 . Criteria

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) confirmed by meeting ONE of the following conditions:

1.1 Assessment of at least one physiologic circadian phase marker [e.g., measurement of

urinary melatonin levels, dim light melatonin onset (as measured in blood or saliva), assessment of core body temperature]

OR

1.2 If assessment of at least one physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient is totally blind (has no light perception) *Requests for patients who are sighted (non-blinded) will be reviewed on a case-by-case basis

AND

3 - Patient is 18 years of age or older

AND

4 - Patient has received at least 3 months of continuous therapy (i.e., 3 consecutive months of daily treatment) under the guidance of a physician who specializes in the treatment of sleep disorders of BOTH of the following:

- Melatonin
- Rozerem (ramelteon)

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule

Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep)

AND

2 - Submission of patient's sleep log demonstrating positive clinical response to therapy

Product Name: Hetlioz capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Submission of test results confirming patient has microdeletion of the chromosome band 17p11.2 by fluorescent in situ hybridization (FISH) analysis

AND

3 - Patient is 16 years of age or older

AND

4 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

5 - Patient has received at least 3 months of continuous therapy (i.e., 3 consecutive months of daily treatment) under the guidance of a physician who specializes in the treatment of sleep disorders of BOTH of the following

- Melatonin
- Rozerem (ramelteon) (unless contraindicated due to patient age)

AND

6 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Submission of test results confirming patient has microdeletion of the chromosome band 17p11.2 by fluorescent in situ hybridization (FISH) analysis

AND

3 - Patient is 3 through 15 years of age

AND

4 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

5 - Patient has received at least 3 months of continuous therapy (i.e., 3 consecutive months of daily treatment) of melatonin under the guidance of a physician who specializes in the treatment of sleep disorders

AND

6 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

AND

2 - Submission of patient's sleep log demonstrating positive clinical response to therapy

2 . Revision History

Date	Notes
11/16/2022	Custom updates to all sections

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-112911
Guideline Name	HIV (Fuzeon, Selzentry)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Brand Selzentry tablets, generic maraviroc 150mg and 300mg tablets, Selzentry oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

AND

2 - For generic maraviroc tablets and Selzentry oral solution ONLY; history of failure or intolerance to Brand Selzentry tablets

Product Name: Fuzeon	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has been diagnosed with multidrug-resistant HIV-1 infection

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

2 . Revision History

Date	Notes
8/29/2022	New Program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144637
Guideline Name	Humira (adalimumab) and adalimumab biosimilars
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Non-Preferred*: Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Brand Adalimumab-fkjp, Hyrimoz, Brand Adalimumab-adaz, Idacio, Yuflyma, Yusimry	
Approval Length	N/A - Requests for Non-Preferred Drugs should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried and failed Humira	
Notes	*Requests for coverage of Non-Preferred drugs are not authorized and will not be approved. Patient must use Humira. All Non preferred products will be denied for appeals process.

Product Name: Humira

Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]

- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Humira	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Humira	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Adult Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2 Patient has lost response or intolerant to infliximab (e.g., Remicade, Inflectra, Renflexis)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Pediatric Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)

- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)

- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Adult Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Humira	
Diagnosis	Hidradenitis Suppurativa
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Hidradenitis Suppurativa
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Humira	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as ONE of the following:

- intermediate
- posterior
- panuveitis

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at a maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

5 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

6 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist

• Ophthalmologist	
Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

2 . Revision History

Date	Notes

3/19/2024	Added new GPI for Yuflyma

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99465
Guideline Name	Hydroxychloroquine
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Plaquenil, generic hydroxychloroquine	
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 Treatment of chronic discoid lupus erythematosus or systemic lupus erythematosus

OR

1.2 Treatment of rheumatoid arthritis

OR **1.3** Prophylaxis of malaria in geographic areas where chloroquine resistance is not reported **OR** **1.4** Treatment of uncomplicated malaria	
Notes	Authorization will be issued for 6 months up to a quantity of 120 tablets per 30 days.

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-114463
Guideline Name	Hyftor (sirolimus) topical gel
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Hyftor	
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of facial angiofibroma associated with tuberous sclerosis complex

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is not a candidate for laser therapy or surgical treatments

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Hyftor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)

2 . Revision History

Date	Notes
9/26/2022	New program

Prior Authorization Guideline

Guideline ID	GL-110775
Guideline Name	Igalmi (dexmedetomidine)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/15/2022

1 . Criteria

Product Name: Igalmi	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Schizophrenia
- Bipolar I or II disorder

AND

2 - For the treatment of acute agitation

AND

3 - Trial and failure, contraindication or intolerance to at least two preferred products used in acute agitation (e.g., olanzapine, ziprasidone)

AND

4 - Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid)

2 . Revision History

Date	Notes
8/4/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-135337
Guideline Name	Ilaris (canakinumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndromes [Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency(MKD), Familial Mediterranean Fever(FMF)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) confirming a diagnosis of one of the following periodic fever syndromes:	

- Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
- Tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)
- Hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS/mevalonate kinase deficiency (MKD)
- Familial Mediterranean Fever (FMF)

AND

2 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Immunologist

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Patients diagnosed with Familial Mediterranean Fever (FMF) have a history of failure, contraindication, or intolerance to colchicine (applies to diagnosis of FMF ONLY)

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy [defined as a decrease in frequency or severity of attacks, or a decrease in index disease flare or normalization of CRP (C-reactive protein)]

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of active systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Immunologist

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following: [1-3]

- Corticosteroids (e.g., prednisone)
- Methotrexate
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Immunologist

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Gout Flares
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of gout flares

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ALL of the following:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)
- Colchicine
- Corticosteroids (e.g., prednisone)

AND

3 - Patient has not received Ilaris in the last 12 weeks [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Nephrologist

2 . Definitions

Definition	Description
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [1, 4, 5]

Familial Cold Autoinflammatory Syndrome (FCAS):	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [5]
Muckle-Wells Syndrome (MWS):	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malaise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [5]

3 . Endnotes

A. The recommended dose of Ilaris for adult patients with a gout flare is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of Ilaris may be administered [1].

4 . Revision History

Date	Notes
10/24/2023	Added criteria for new indication of gout flares. Updated criteria for all indications.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99718
Guideline Name	Ilumya - Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ilumya	
Diagnosis	Chronic Moderate to Severe Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure, to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Ilumya therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Ilumya	
Diagnosis	Chronic Moderate to Severe Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ilumya therapy

AND

2 - Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-139335
Guideline Name	Imcivree (setmelanotide)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Imcivree	
Diagnosis	POMC, PCSK1, LEPR Deficiency
Approval Length	n/a- requests for indications other than Bardet-Biedl syndrome (BBS) are excluded from coverage and will not be approved.
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for indications other than Bardet-Biedl syndrome (BBS) are excluded from coverage and will not be approved.	
Notes	Requests for indications other than Bardet-Biedl syndrome (BBS) are excluded from coverage and will not be approved.

Product Name: Imcivree	
Diagnosis	Bardet-Biedl syndrome (BBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Both of the following:

- Diagnosis of Bardet-Biedl syndrome (BBS)
- Molecular genetic testing to confirm homozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted)

AND

1.2 One of the following:

1.2.1 Patient has at least three of the following primary features of the disease:

- Rod-cone dystrophy
- polydactyly
- learning disabilities
- hypogonadotropic hypogonadism and/or genitourinary anomalies
- renal anomalies

OR

1.2.2 Both of the following:

1.2.2.1 Patient has at least two of the following primary features of the disease:

- Rod-cone dystrophy
- polydactyly
- learning disabilities
- hypogonadotropic hypogonadism and/or genitourinary anomalies
- renal anomalies

AND

1.2.2.2 Patient has at least two of the following secondary features of the disease:

- Speech disorder/delay
- strabismus/cataracts/astigmatism
- brachydactyly/syndactyly
- developmental delay
- ataxia/poor coordination/imbalance
- mild spasticity (especially lower limbs)
- diabetes mellitus
- dental crowding/hypodontia/small roots/high arched palate
- left ventricular hypertrophy/congenital heart disease
- hepatic fibrosis

AND

1.3 Patient has been diagnosed with obesity defined by one of the following:

- BMI greater than or equal to 30 kg/m2 for adults 18 years of age or older
- Weight greater than or equal to 95th percentile using growth chart assessments for pediatric patients

AND

1.4 Patient is 6 years of age or older

AND

1.5 Other causes or types of obesity have been ruled out (e.g., obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign; obesity associated with other genetic syndromes; polygenic obesity)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Requests for indications other than Bardet-Biedl syndrome (BBS) are excluded from coverage and will not be approved.

Product Name: Imcivree	
Diagnosis	Bardet-Biedl syndrome (BBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

1.1 Patient has been on therapy for 12 months or more

AND

1.2 Weight loss of greater than or equal to 5% of baseline body weight or BMI

Notes	Requests for indications other than Bardet-Biedl syndrome (BBS) are excluded from coverage and will not be approved.

2 . Revision History

Date	Notes
1/23/2024	new program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143257
Guideline Name	Immune Globulins - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Asthma (severe, persistent, high-dose steroid-dependent)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Severe asthma

- Persistent asthma
- High-dose steroid-dependent asthma

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient is receiving optimal conventional asthma therapy (e.g., high-dose inhaled glucocorticoids, short- and long-acting inhaled β agonists)

AND

4 - History of failure, contraindication, or intolerance to at least TWO of the following:

- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

5 - Patient has required continuous oral glucocorticoid therapy for a minimum of 2 months prior to the decision to initiate immune globulin therapy

AND

6 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

7 - Prescribed by or in consultation with a pulmonologist or allergist or immunologist

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Asthma (severe, persistent, high-dose steroid-dependent)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Extensive and debilitating disease

AND

4 - History of failure, contraindication, or intolerance to systemic corticosteroids with

concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil)

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 to 2,000 milligrams (mg) per kilogram (kg) per month divided into 3 equal doses, each given over 3 consecutive days or 400 mg per kg per day given over 5 consecutive days per month. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

6 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Bone Marrow Transplant (BMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following uses:

- Prevention of acute graft vs. host disease (GVHD)
- Prevention of infection

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Confirmed allogeneic bone marrow transplant within the last 100 days

AND

4 - Documented severe hypogammaglobulinemia [Immunoglobulin (IgG) less than 400 milligrams (mg) per deciliter (dL)]

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 500 mg per kilogram (kg) once weekly for the first 90 days of therapy, then monthly up to 360 days after transplantation

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Bone Marrow Transplant (BMT)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by ALL of the following:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb

AND

1.3 Electrodiagnostic findings [consistent with European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) guidelines for definite chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)] indicating at least ONE of the following criteria are present:

- Motor distal latency prolongation in 2 nerves
- Reduction of motor conduction velocity in 2 nerves
- Prolongation of F-wave latency in 2 nerves
- Absence of F-waves in at least 1 nerve
- Partial motor conduction block of at least 1 motor nerve
- Abnormal temporal dispersion in at least 2 nerves
- Distal compound muscle action potential (CMAP) duration increase in at least 1 nerve

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in B-cell Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL)

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - ONE of the following:

- Documented hypogammaglobulinemia [Immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]

- History of bacterial infection(s) associated with B-cell CLL

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 milligrams (mg) per kilogram (kg) every 3 to 4 weeks

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in B-cell Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Dermatomyositis or polymyositis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatomyositis or polymyositis

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate)

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days administered as monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

5 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Dermatomyositis or polymyositis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is newly diagnosed with insulin dependent (type 1) diabetes mellitus

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient is not a candidate for or is refractory to insulin therapy

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Feto-neonatal Alloimmune Thrombocytopenia (AIT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For pregnant women ALL of the following:

1.1.1 Diagnosis of feto-neonatal alloimmune thrombocytopenia (AIT)

AND

1.1.2 ONE of the following:

- Previously affected pregnancy
- Family history of the disease
- Platelet alloantibodies found on screening

AND

1.1.3 ONE of the following:

1.1.3.1 Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) once weekly until delivery

OR

1.1.3.2 BOTH of the following:

- Fetus or newborn is considered to be at high risk for developing intracranial hemorrhage or other severe complication of AIT
- IVIG dose does not exceed 2,000 mg/kg once weekly until delivery

OR

1.2 For newborns BOTH of the following:

1.2.1 Diagnosis of feto-neonatal alloimmune thrombocytopenia

AND

1.2.2 Thrombocytopenia that persists after transfusion of antigen-negative compatible platelets

AND

2 - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen

- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Feto-neonatal Alloimmune Thrombocytopenia (AIT)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Graves' ophthalmopathy Guillain-Barré syndrome (GBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Guillain-Barré Syndrome

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Severe disease requiring aid to walk

AND

4 - Onset of neuropathic symptoms within the last four weeks

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Graves' ophthalmopathy Guillain-Barré syndrome (GBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of bacterial infection in pediatric HIV
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV disease

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient age less than or equal to 13 years of age

AND

4 - ONE of the following:

- Documented hypogammaglobulinemia [Immunoglobulin (IgG) less than 400 milligrams (mg) per deciliter (dL)]

- Functional antibody deficiency as demonstrated by either poor specific antibody titers or recurrent bacterial infections

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 28 days

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of bacterial infection in pediatric HIV
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Immune thrombocytopenia [Idiopathic thrombocytopenic purpura (ITP)]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

- Diagnosis of acute thrombocytopenic purpura (ITP)
- Documented platelet count less than 50 x 10^9 per Liter (L) (obtained within the past 30 days)
- Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram(kg) per day for 1 to 2 days

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic thrombocytopenic purpura (ITP)

AND

1.2.2 History of failure, contraindication, or intolerance to at least ONE of the following:

- Corticosteroids
- Splenectomy

AND

1.2.3 IVIG dose does not exceed 2,000 mg per kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Immune thrombocytopenia [Idiopathic thrombocytopenic purpura (ITP)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Kawasaki Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Kawasaki disease

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 4,000 milligrams (mg) per kilograms (kg) for five consecutive days or a single dose of 2,000 mg per kg

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Kawasaki Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids)

AND

4 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous Immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C

- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lennox Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication or intolerance to initial treatment with traditional anti-epileptic pharmacotherapy (e.g., lamotrigine, phenytoin, valproic acid)

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 milligrams (mg) per kilogram (kg) per day given for 4 to 5 consecutive days. IVIG administration may be repeated monthly as needed in patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

5 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lennox Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Multifocal Motor Neuropathy (MMN)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy as confirmed by ALL of the following:

- Weakness with slowly progressive or stepwise progressive course over at least one month
- Asymmetric involvement of two or more nerves
- Absence of motor neuron signs and bulbar signs

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,400 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Multifocal Motor Neuropathy (MMN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,400 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

4 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - ONE of the following:

- Documented hypogammaglobulinemia [immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with multiple myeloma

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 3 to 4 weeks

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Relapsing Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary- progressive MS with relapses, progressive-relapsing MS with relapses)

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy

AND

4 - History of failure, contraindication, or intolerance to at least TWO of the following agents:

- Aubagio (teriflunomide)
- Avonex (interferon beta-1a)

- Betaseron (interferon beta-1b)
- Copaxone/Glatopa (glatiramer acetate)
- Extavia (interferon beta-1b)
- Gilenya (fingolimod)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Mayzent (siponimod)
- Ocrevus (ocrelizumab)
- Plegridy (peginterferon beta-1a)
- Rebif (interferon beta-1a)
- Tecfidera (dimethyl fumarate)
- Tysabri (natalizumab)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Induction, when indicated, does not exceed a dose of 400 milligrams (mg) per kilogram (kg) daily for up to five days

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Relapsing Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical records, including findings of interval examination including neurological deficits incurred and assessment of disability [e.g., Expanded Disability Status Scale (EDSS), Functional Systems Score (FSS), Multiple Sclerosis Functional Composite (MSFC), Disease Steps (DS)]

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS)

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy

AND

4 - Diagnosis continues to be the relapsing forms of multiple sclerosis (MS)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligram (mg) per kilogram (kg) monthly

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Myasthenia Gravis - Exacerbation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Evidence of myasthenia exacerbation, defined by at least ONE of the following symptoms in the last month

- Difficulty swallowing
- Acute respiratory failure
- Major functional disability responsible for the discontinuation of physical activity

- Recent immunotherapy treatment with a checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)]

AND

4 - ONE of the following:

- History of failure, contraindication, or intolerance to immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis
- Currently receiving immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembfiy

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Refractory Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory generalized myasthenia gravis by or in consultation with a physician or center with expertise in management of myasthenia gravis

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documentation that the disease status is unchanged or worsening (persistent or worsening symptoms that limit functioning) despite failure, contraindication, or intolerance to BOTH of the following (used in adequate doses and duration):

- Corticosteroids
- Two immunomodulator therapies (e.g., azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus)

AND

4 - Currently receiving immunomodulator therapy (e.g., corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus), used in adequate doses, for long-term management of myasthenia gravis

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Myasthenia Gravis –Exacerbation and Refractory Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Neuromyelitis Optica
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist confirming ALL of the following:

1.1 Serologic testing for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) or Neuromyelitis optica immunoglobulin G (NMO-IgG) antibodies has been performed

AND

1.2 ONE of the following:

1.2.1 If AQP4-IgG/NMO-IgG positive, past medical history of ONE of the following:

- Optic neuritis
- Acute myelitis

- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

OR

1.2.2 If AQP4-IgG/NMO-IgG negative, past medical history of TWO of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

1.3 Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to at least TWO of the following:

- Azathioprine
- Corticosteroids
- Mycophenolate mofetil
- Rituximab

- Soliris (eculizumab)

AND

4 - Patient is not receiving immune globulin in combination with either of the following:

- Rituximab
- Soliris (eculizumab)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligram (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Neuromyelitis Optica
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with immune globulin

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by BOTH of the following:

2.1 Reduction in the number and or severity of relapses or signs and symptoms of neuromyelitis optica spectrum disorder (NMOSD)

AND

2.2 Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting immune globulin. (NOTE: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on immune globulin therapy will be considered as treatment failure.)

AND

3 - Patient is not receiving immune globulin in combination with either of the following:

- Rituximab
- Soliris (eculizumab)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Posttransfusion Purpura
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of posttransfusion purpura

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) for 2 days

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Posttransfusion Purpura
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Post B-Cell Targeted Therapies
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation confirming previous treatment of B-cell targeted therapy within the last 100 days [e.g., CAR-T (e.g., Kymriah), Rituxan (rituximab), Besponsa (inotuzumab ozogamicin)]

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - BOTH of the following:

- Documented hypogammaglobulinemia [immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with B-cell depletion

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 4 weeks, up to 360 days after discontinuation of B-cell depleting therapy

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Post B-Cell Targeted Therapies
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Primary Immunodeficiency Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunodeficiency

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by ONE of the following:

- Documented failure to produce antibodies to specific antigens
- History of significant recurrent infections

AND

4 - Initial intravenous immunoglobulin (IVIG) dose is 200 to 800 milligrams (mg) per kilogram (kg) every 3 to 4 weeks, based on product prescribing information, and titrated based upon patient response (For subcutaneous immune globulin (SCIG) products, FDA-labeled dosing and conversion guidelines will used to determine benefit coverage.)

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Primary Immunodeficiency Syndromes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Rasmussen Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following demonstrating that:

- Short term amelioration of encephalitis is needed prior to definitive surgical therapy
- Disease symptoms (e.g., seizures) persist despite surgical treatment
- The patient is not a candidate for surgical treatment

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Rasmussen Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Stiff-Person Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stiff-person syndrome

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication or intolerance to GABAergic (gamma-aminobutyric acid analogs) medication (e.g., baclofen, benzodiazepines)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Stiff-Person Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical improvement from baseline

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per

kilogram (kg) per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

4 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Thrombocytopenia, secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of thrombocytopenia secondary to Hepatitis C Virus (HCV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.2 Both of the following:

- Diagnosis of thrombocytopenia secondary Human Immunodeficiency Virus (HIV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.3 Diagnosis of thrombocytopenia secondary to pregnancy

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documented platelet count less than 50 x 10^9 per liter (L) (obtained within the past 30 days)

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) per day for 1 to 2 days

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam
- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Thrombocytopenia, secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of thrombocytopenia secondary to Hepatitis C Virus (HCV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.2 Both of the following:

- Diagnosis of thrombocytopenia secondary Human Immunodeficiency Virus (HIV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.3 Diagnosis of thrombocytopenia secondary to pregnancy

AND

2 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	All other indications
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Autoimmune Uveitis
- Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants
- Enteroviral Meningoencephalitis
- IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Lymphoproliferative disease (treatment of bacterial infections)
- Monoclonal gammopathy
- Paraproteinemic neuropathy
- Renal transplantation (prevention or treatment of acute humoral rejection)
- Severe Rheumatoid arthritis
- Rotaviral enterocolitis
- Staphylococcal toxic shock
- Toxic epidermal necrolysis or Stevens-Johnson syndrome
- Urticaria (delayed pressure)

AND

2 - Submission of medical records(e.g., chart notes) documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products:

- Bivigam

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra
- Octagam
- Privigen
- Xembify

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	All other indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

2 . Revision History

Date	Notes

2/28/2024	Updated criteria formatting for AIT indication. Updated preferred prer equisites t/f reqs throughout guideline. Added Submission of medical records verbiage to clarify medical records criterion (2).

Prior Authorization Guideline

Guideline ID	GL-99466
Guideline Name	Inbrija
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Inbrija	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson’s disease

AND

2 - Inbrija will be used as intermittent treatment for OFF episodes

AND

3 - Prescribed by, or in consultation with, a neurologist or specialist in the treatment of Parkinson's disease

AND

4 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

5 - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

6 - History of failure, contraindication, or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

Product Name: Inbrija	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inbrija therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-135431
Guideline Name	Infliximab Products
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of active PsA

AND

2 - One of the following:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy as evidenced by ONE of the following:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of one of the following:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Infliximab (Janssen manufacturer) *DOES NOT APPLY TO REQUESTS FOR INFLIXIMAB (JANSSEN MANUFACTURER)

Product Name: Avsola, Inflectra, Infliximab (Janssen manufacturer), Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

2 . Revision History

Date	Notes
10/25/2023	Updated Infliximab naming convention. No changes to clinical criteria .

Prior Authorization Guideline

Guideline ID	GL-135332
Guideline Name	Ingrezza (valbenazine)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Ingrezza	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia (TD) secondary to a centrally acting dopamine receptor blocking agent (DRBA)

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of the AIMS items 1 through 9

AND

5 - Ingrezza is not prescribed concurrently with Austedo or tetrabenazine

AND

6 - Dose does not exceed 80 mg per day

Product Name: Ingrezza	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline AIMS score in any one of the AIMS items 1 through 9

AND

2 - Ingrezza is not prescribed concurrently with Austedo or tetrabenazine

AND

3 - Dose does not exceed 80 mg per day

Product Name: Ingrezza	
Diagnosis	Chorea Associated with Huntington's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is 18 years of age or older

AND

4 - Dose does not exceed 80 mg per day

Product Name: Ingrezza

Diagnosis	Chorea Associated with Huntington’s Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Dose does not exceed 80 mg per day.

2 . Revision History

Date	Notes
10/23/2023	Added new criteria for new indication of chorea associated with Huntington's Disease

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Prior Authorization Guideline

Guideline ID	GL-105180
Guideline Name	Inhaled Corticosteroids - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Alvesco, Arnuity Ellipta, Asmanex HFA, Qvar Redihaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - History of failure, contraindication, intolerance to a majority (not more than 3) of the preferred inhaled corticosteroids:

- Asmanex Twisthaler (mometasone)
- Flovent Diskus (fluticasone)
- Flovent HFA (fluticasone)
- Pulmicort Flexhaler (budesonide)
- budesonide respule (generic)

2 . Revision History

Date	Notes
3/24/2022	Removed Pulmicort and budesonide respules as targets

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144625
Guideline Name	Injectable Oncology Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD) • Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Injectable Oncology Drugs: Abraxane, Adcetris, Brand Alimta, generic pemetrexed, Bavencio, Belrapzo, Bendeka, Brand Bicnu, generic carmustine, Brand Bortezomib, Breyanzi, Brand Carmustine, Carvykti, Columvi, cyclophosphamide, Docetaxel, Elahere, Elrexfio, Enhertu, Epkinly, Folotyn, Brand Hycamtin injection, generic topotecan injection, Imfinzi, Imjudo, Jemperli, Keytruda, Kymriah, Kyprolis, Libtayo, Loqtorzi, Lunsumio, Onivyde, Opdivo, Paclitaxel, Brand Pemetrexed, Brand Pemfexy, Pemrydi RTU, Polivy, Pralatrexate, Rybrevant, Synribo, Talvey, Tecentriq, Tecvayli, Temodar IV, Brand Treanda, generic bendamustine, Trodelvy, Brand Velcade, generic bortezomib, Brand Vidaza, generic azacitidine, Vivimusta, Yervoy, Yescarta, Zynyz	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
3/27/2024	Added targets: Onivyde, Pemrydi RTU, Rybrevant.

Prior Authorization Guideline

Guideline ID	GL-99682
Guideline Name	Inlyta
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Inlyta	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of renal cell cancer	

AND

2 - One of the following:

2.1 Disease has relapsed

OR

2.2 Diagnosis of Stage IV disease

Product Name: Inlyta	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnosis:

- Follicular Carcinoma
- Hürthle Cell Carcinoma
- Papillary Carcinoma

AND

2 - ONE of the following:

- Unresectable recurrent
- Persistent locoregional disease
- Metastatic disease

AND

3 - Disease is refractory to radioactive iodine treatment

Product Name: Inlyta	
Diagnosis	Advanced Renal Cell Carcinoma, Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Product Name: Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Inlyta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inlyta therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-123725
Guideline Name	Insulin Glargine Products (Basaglar, Rezvoglar, Semglee, Toujeo Solostar, Toujeo Max Solostar)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Basaglar, Rezvoglar, Semglee, Toujeo Solostar, Toujeo Max Solostar	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for Basaglar, Rezvoglar, Semglee, Toujeo Solostar, Toujeo Max Solostar should be denied. The plan's preferred products are:

- Lantus
- Lantus Solostar
- Levemir
- Levemir FlexPen

- Humulin R U 500 (PA Required)

2 . Revision History

Date	Notes
3/23/2023	Updated guideline name. Added Rezvoglar as NP target. Updated pr oduct list.

Prior Authorization Guideline

Guideline ID	GL-99580
Guideline Name	Insulins, Concentrated- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Humulin R U-500 vial and kwikpen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, intolerance, or contraindication to ALL of the following:

- Novolog or Humalog
- Lantus
- Levemir

OR **2** - There is a reason or special circumstance the patient needs to use a concentrated insulin product

2 . Revision History

Date	Notes
8/4/2021	Update guideline

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-104870
Guideline Name	Iron Chelators
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/17/2022

1 . Criteria

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox

Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of transfusional iron overload due to thalassemia syndromes

AND

1.2 Current chelation therapy is inadequate [e.g., Desferal (deferoxamine), Exjade (deferasirox)]

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome

AND

1.2 Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade or Jadenu

AND

1.3 Patient has serum ferritin levels consistently greater than 300 micrograms per liter prior to initiation of treatment with Exjade or Jadenu

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/16/2022	Added new generic deferiprone tabs

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Prior Authorization Guideline

Guideline ID	GL-99468
Guideline Name	Irritable Bowel Syndrome-Diarrhea
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Lotronex, generic alosetron	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

2 - Symptoms for at least 6 months

AND

3 - Patient was female at birth

AND

4 - Age greater than or equal to 18 years

AND

5 - History of failure, contraindication, or intolerance to TWO of the following:

- Antispasmodic agent (e.g. dicyclomine)
- Antidiarrheal agents (e.g. loperamide)
- Tricyclic antidepressant (e.g. amitriptyline)

Product Name: Brand Lotronex, generic alosetron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lotronex therapy

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AND

2 - History of failure, contraindication, or intolerance to TWO of the following:

- Antispasmodic agent (e.g. dicyclomine)
- Antidiarrheal agents (e.g. loperamide)
- Tricyclic antidepressant (e.g. amitriptyline)

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Viberzi therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-125300
Guideline Name	Isotretinoin - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/6/2023

1 . Criteria

Product Name: Brand Absorica, Absorica LD, Accutane, Amnesteem, Claravis, generic isotretinoin, Myorisan, Zenatane	
Diagnosis	Oncology Uses (Off Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for oncology indication meeting National Comprehensive Cancer Network (NCCN) with a Category of Evidence and Consensus of 1, 2A, or 2B. or from ONE of the following appropriate compendia of current literature: American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex, or Clinical Pharmacology

Product Name: Brand Absorica, Absorica LD, Accutane, Amnesteem, Claravis, generic isotretinoin, Myorisan, Zenatane	
Approval Length	5 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

OR

1.2 Diagnosis of treatment resistant acne

AND

2 - History of failure, contraindication, or intolerance to an adequate trial on TWO of the following conventional therapy regimens:

- Topical retinoid or retinoid-like agent [eg,Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [eg, Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

AND

3 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (see table in Background section)

Product Name: Brand Absorica, Absorica LD, Accutane, Amnesteem, Claravis, generic isotretinoin, Myorisan, Zenatane	
Diagnosis	Persistent or Recurring Acne After 2 Months Off Therapy

Approval Length	5 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - After greater than or equal to 2 months OFF therapy, persistent or recurring severe recalcitrant nodular acne is still present	
Notes	Authorization will be given only by clinical pharmacist review for up to 5 months.

Product Name: Brand Absorica, Absorica LD, Accutane, Amnesteem, Claravis, generic isotretinoin, Myorisan, Zenatane	
Diagnosis	Dose Titration
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Confirmation that the cumulative dose is less than 150 mg/kg (there is little therapeutic benefit to be gained by increasing the cumulative dose beyond 150 mg/kg)*	
Notes	Authorization will be given only by clinical pharmacist review for 1 mo nth to allow for titration up to the target dose *See background section for dosing regimens

2 . Background

Benefit/Coverage/Program Information
Formulary **Preferred Agents:**

Accutane, Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin), generic isotretinoin

Non-Preferred Agents:

Absorica (isotretinoin)

Absorica LD (isotretinoin)

Dosing by Body Weight (based on administration with food):

Body Weight		Daily Dose		
Kg	Lbs	0.5 mg/kg/day	1 mg/kg/day	2 mg/kg/day
40	88	20	40	80
50	110	25	50	100
60	132	30	60	120
70	154	35	70	140
80	176	40	80	160
90	198	45	90	180
100	220	50	100	200

3 . Revision History

Date	Notes
5/5/2023	Added Accutane as target

Prior Authorization Guideline

Guideline ID	GL-99684
Guideline Name	Isturisa
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Both of the following:	

1.1 Diagnosis of Cushing's disease

AND

1.2 ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to Isturisa therapy

Product Name: Isturisa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Isturisa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Isturisa

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Isturisa therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-135329
Guideline Name	Izervay (avacincaptad pegol)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Izervay	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) as confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)

- Fluorescein angiography

AND

2 - GA is not secondary to any other conditions (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Izervay	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

AND

2 - Patient has not exceeded a total of 12 months treatment

2 . Revision History

Date	Notes
10/23/2023	New program

Prior Authorization Guideline

Guideline ID	GL-143522
Guideline Name	Jesduvroq (daprodustat)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Jesduvroq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient has been on dialysis for at least 4 months

AND

3 - Adequate iron stores confirmed by both of the following:

- Patient's ferritin level is greater than 100mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL

AND

5 - Trial and failure, contraindication or intolerance to one of the following:

- Epogen
- Procrit
- Retacrit

AND

6 - Prescribed by or in consultation with one of the following:

- hematologist
- nephrologist

AND

7 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

Product Name: Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in hemoglobin)

AND

2 - Hemoglobin level does not exceed 12g/dL

AND

3 - Adequate iron stores confirmed by both of the following:

- Patient's ferritin level is greater than 100mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

2 . Revision History

Date	Notes
2/28/2024	New program

Prior Authorization Guideline

Guideline ID	GL-127086
Guideline Name	Joenja (leniolisib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Joenja	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

AND

1.2 Molecular genetic testing confirms mutations in the PIK3CD or PIK3R1 gene

AND

1.3 Both of the following:

- Presence of nodal and/or extranodal proliferation (e.g., lymphadenopathy, splenomegaly, hepatomegaly)
- Presence of other clinical findings and manifestations consistent with APDS (e.g., recurrent sino-pulmonary infections, bronchiectasis, enteropathy)

AND

1.4 Trial and failure, contraindication, or intolerance to at least one standard of care treatment for APDS (e.g., Immunoglobulin replacement therapy, antimicrobial prophylaxis [e.g., azithromycin, bactrim], rituximab, tacrolimus, etc.)

AND

2 - Patient is 12 years of age or older

AND

3 - Patient weighs greater than or equal to 45kg

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Immunologist

Product Name: Joenja	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased severity or frequency of infections/hospitalizations)

2 . Revision History

Date	Notes
6/26/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99791
Guideline Name	Juxtapid - AZ
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment low density lipoprotein cholesterol (LDL-C) greater than 500 milligrams per deciliter

- Treated LDL-C greater than 300 milligrams per deciliter

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Patient has tried, failed or intolerant to Repatha and Praluent

AND

6 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

Notes	Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is continuing a low-fat diet and exercise regimen

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, low density lipoprotein [LDL] apheresis)

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Juxtapid therapy

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

2 . Revision History

Date	Notes
7/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-100644
Guideline Name	Jynarque
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)	

Product Name: Jynarque, Jynarque Pak

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jynarque therapy

2 . Revision History

Date	Notes
12/16/2021	Added new Jynarque GPIs

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Prior Authorization Guideline

Guideline ID	GL-135314
Guideline Name	Kalydeco (ivacaftor)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Kalydeco, Kalydeco packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient has ONE of the mutations in the

cystic fibrosis transmembrane conductance regulator (CFTR) gene listed in the table in the Background section:

AND

3 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Kalydeco, Kalydeco packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Kalydeco therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, specialist affiliated with a cystic fibrosis (CF) care center

2 . Background

Benefit/Coverage/Program Information
CFTR Gene Mutations that are Responsive to Kalydeco
List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDE

*711+3A→G **	*F311del*	*I148T*	*R75Q*	*S589N*
*2789+5G→A **	*F311L*	*I175V*	*R117C **	*S737F*
*3272-26A→G **	*F508C*	*I807M*	*R117G*	*S945L **
*3849+10kbC→T **	*F508C;S1251N †*	*I1027T*	*R117H **	*S977F **
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W **	*R170H*	*S1251N **
*A455E **	*G178R **	*L320V*	*R347H **	*S1255P **
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q **	*T1053I*
D110H	*G551D **	*L1480P*	*R553Q*	*V232D*
D192G	*G551S **	*M152V*	*R668C*	*V562I*
*D579G **	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H **	*G1069R*	*P67L **	*R1070Q*	*W1282R*
D1270N	*G1244E **	*Q237E*	*R1070W **	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D **	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N **	
*E831X **	*H1375P*	*R74W*	*S549R **	

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes
10/23/2023	Added GPI for 5.8 mg packs

Prior Authorization Guideline

Guideline ID	GL-137600
Guideline Name	Katerzia, Norliqva (amlodipine oral solution)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Katerzia, Norliqva	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 8 years of age or younger

OR

1.2 Both of the following:

1.2.1 Requested medication is being used for one of the following diagnoses:

- Hypertension
- Chronic stable angina
- Confirmed or suspected vasoplastic angina
- Angiographically documented Coronary Artery Disease (CAD)

AND

1.2.2 One of the following:

1.2.2.1 Trial and failure, contraindication, or intolerance to generic amlodipine tablets (verified via paid pharmacy claims or submitted chart notes)

OR

1.2.2.2 Patient is unable to swallow oral tablets/capsules

AND

2 - For Norliqva requests: trial and failure, contraindication, or intolerance to Katerzia (verified via paid pharmacy claims or submitted chart notes) APPLIES TO NORLIQVA REQUESTS ONLY

2 . Revision History

Date	Notes
12/11/2023	Added step through Katerzia for Norliqva (now NP).

Prior Authorization Guideline

Guideline ID	GL-136964
Guideline Name	Kepivance (palifermin)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Kepivance	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Medication will be used to prevent or treat severe (WHO Grade 3 or higher) oral mucositis

AND

1.2 Inadequate response to an oral mouthwash formulated with diphenhydramine/antacid and lidocaine (e.g., magic or miracle mouthwash)

AND

2 - Prescribed by a hematologist or oncologist

2 . Revision History

Date	Notes
12/1/2023	New program

Prior Authorization Guideline

Guideline ID	GL-126131
Guideline Name	Kerendia (finerenone)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

AND

2 - Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g

AND

3 - Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2

AND

4 - Serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment

AND

5 - One of the following:

5.1 Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following [2]:

- Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB

OR

2.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

2 . Revision History

Date	Notes
5/30/2023	Updated initial auth criteria

Prior Authorization Guideline

Guideline ID	GL-99621
Guideline Name	Keveyis
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of primary hyperkalemic periodic paralysis or related variant

OR

1.2 Diagnosis of primary hypokalemic periodic paralysis or related variant

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Keveyis therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-125025
Guideline Name	Kevzara - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Kevzara	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g. chart notes) documenting ALL of the following:

1.1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to ALL of the following (paid pharmacy claims may be used to confirm trials):

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.1.4 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Kevzara therapy as documented by claims history or medical records (document date and duration of therapy)

AND

1.2.2 Diagnosis of moderately to severely active RA

AND

1.2.3 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Kevzara	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy as evidenced by at least one of the following

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Kevzara 200 mg	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of polymyalgia rheumatica (PMR)

AND

2 - One of the following:

2.1 Patient has had an inadequate response to corticosteroids (e.g., prednisone)

OR

2.2 Patient cannot tolerate tapering of corticosteroids (e.g., prednisone)

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Kevzara 200 mg	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in symptoms (e.g., pain, stiffness) or lab values (e.g., C-reactive protein) from baseline
- Reduced need for corticosteroids (e.g., prednisone)

AND

2 - Prescribed by or in consultation with a rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

2 . Revision History

Date	Notes
4/25/2023	Added criteria for PMR. Updated RA criteria.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-104978
Guideline Name	Kimmtrak (tebentafusp-tebn)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Kimmtrak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of uveal melanoma

AND

2 - Disease is unresectable or metastatic

AND

3 - Patient is HLA-A*02:01 genotype positive as determined by a high-resolution genotyping test [2]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Kimmtrak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient does not show evidence of progressive disease while on therapy

2 . Revision History

Date	Notes
3/22/2022	New Program mirrors ORx with Submission of Records added to initi al and reauth

Prior Authorization Guideline

Guideline ID	GL-114542
Guideline Name	Kineret (anakinra)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., Rheumatrex/Trexall [methotrexate], Arava [leflunomide], Azulfidine [sulfasalazine])

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- Humira (adalimumab)
- Xeljanz (tofacitinib)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Orencia (abatacept)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Kineret therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Diagnosis of NOMID has been confirmed by one of the following:

2.1 NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation

OR

2.2 Both of the following:

2.2.1 Two of the following clinical symptoms:

- Urticaria-like rash
- Cold/stress triggered episodes
- Sensorineural hearing loss
- Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia)
- Chronic aseptic meningitis
- Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing)

AND

2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])

AND

3 - Prescribed by or in consultation with one of the following

- Allergist/Immunologist
- Rheumatologist
- Pediatrician

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming the diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following:

- Nonsteroidal anti-inflammatory drug (NSAID) (e.g., Motrin [ibuprofen], Naprosyn [naproxen])
- Systemic glucocorticoid (e.g., prednisone)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
9/26/2022	Updated criteria, created new criteria for DIRA

Prior Authorization Guideline

Guideline ID	GL-99622
Guideline Name	Korlym
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of Endogenous Cushing's Syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 ONE of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

1.3 ONE of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following:

- Patient has improved glucose tolerance while on Korlym therapy
- Patient has stable glucose tolerance while on Korlym therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-107424
Guideline Name	Korsuva (difelikefalin)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Korsuva	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of chronic kidney disease (CKD)

AND

1.2 Patient is currently undergoing hemodialysis (HD) at an optimal dialysis dose (e.g., Kt/V greater than or equal to 1.2)

AND

1.3 Patient is experiencing moderate to severe pruritus associated with CKD (CKD-aP)

AND

1.4 Exclusion of other causes of pruritus (e. g., eczema, infections, drug-induced skin dryness)

AND

1.5 Trial and failure, contraindication, or intolerance to ONE topical anti-pruritic treatment:

- emollient cream
- analgesics (e.g., pramoxine lotion, capsaicin)
- corticosteroids (e.g., hydrocortisone, triamcinolone)

AND

1.6 Trial and failure, contraindication, or intolerance to ONE oral treatment*:

- antihistamine (e.g., diphenhydramine, hydroxyzine, loratadine)
- gabapentin
- pregabalin

AND

2 - Prescribed by or in consultation with one of the following:

- Nephrologist

• Dermatologist	
Notes	*PA may be required

Product Name: Korsuva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Patient is currently undergoing hemodialysis

AND

1.2 Documentation of positive clinical response to therapy (e.g., improved quality of life, improved worst itching intensity numerical rating score from baseline)

2 . Revision History

Date	Notes
5/24/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-117642
Guideline Name	Krystexxa (pegloticase)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Krystexxa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gout

AND

2 - Submission of medical records (e.g., chart notes) confirming trial and failure,

contraindication, or intolerance to maximum recommended doses to both of the following conventional therapies:

- Xanthine oxidase inhibitor (i.e., allopurinol, febuxostat)
- Uricosuric agent (e.g., probenecid)

AND

3 - Submission of medical records (e.g., chart notes) documenting one of the following:

- History of at least two gout flares in the previous 12 months
- At least 1 gouty tophus

AND

4 - Prescribed by or in consultation with a rheumatologist or nephrologist

Product Name: Krystexxa	
Approval Length	12 Months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g, chart notes) documenting positive clinical response to Krystexxa therapy demonstrated by both of the following:

- Serum urate level has decreased since initiating therapy
- Clinical improvement in the signs and symptoms of gout (e.g., decrease in tophi size or frequency of gouty flares per year from baseline or improvement in chronic arthropathy or quality of life)

2 . Revision History

Date	Notes

12/4/2022	New program

Prior Authorization Guideline

Guideline ID	GL-99623
Guideline Name	Kuvan
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kuvan	
Diagnosis	Phenylketonuria (PKU)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-112081
Guideline Name	LAMA, LABA - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Anoro, Bevespi, Stiolto	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to treatment with a 30 day trial of a long-acting beta-agonist (e.g. Foradil, Serevent, Striverdi, Arcapta)

OR

2.2 History of failure, contraindication, or intolerance to treatment with a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza)

AND

3 - For Bevespi requests ONLY: history of failure, contraindication, or intolerance to treatment with a 30 day trial of both of the following Preferred drugs:

- Anoro Ellipta
- Stiolto Respimat

2 . Revision History

Date	Notes
8/22/2022	Added Anoro Ellipta as target. Added criteria for Bevespi.

Prior Authorization Guideline

Guideline ID	GL-125941
Guideline Name	Lamzede (velmanase alfa-tycv)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Lamzede	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of alpha-mannosidosis

AND

2 - Submission of medical records (e.g., chart notes) confirming diagnosis by one of the following:

- Deficiency in alpha-mannosidase enzyme activity as measured in fibroblasts or leukocytes
- Molecular genetic testing confirms mutations in the MAN2B1 gene

AND

3 - Treatment is only for non-central nervous system disease manifestations (e.g., large head, prominent forehead, protruding jaw, skeletal abnormalities)

Product Name: Lamzede	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming patient does not show evidence of progressive disease while on therapy as evidenced by one of the following:

- Reduction in serum oligosaccharide concentration from baseline
- Improvement in clinical signs and symptoms from baseline (e.g., 3-minute stair climbing test, 6-minute walking test, pulmonary function, quality of life)

2 . Revision History

Date	Notes
5/22/2023	New program

Prior Authorization Guideline

Guideline ID	GL-136956
Guideline Name	Lantidra (donislecel-jujn)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Lantidra	
Approval Length	One Time Approval
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of Type 1 diabetes

AND

1.2 Patient is insulin dependent

AND

1.3 Patient is unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education

AND

1.4 Patient has reduced awareness of hypoglycemia, as defined by the absence of adequate autonomic symptoms at glucose levels of less than 54 mg/dL

AND

1.5 Patient has had at least one episode of severe hypoglycemia in the past 3 years with both of the following:

1.5.1 Patient required assistance of another person

AND

1.5.2 One of the following:

1.5.2.1 Symptoms were associated with a blood glucose level less than 50 mg/dL

OR

1.5.2.2 Prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration

AND

1.6 Patient will be on concomitant immunosuppression (e.g., daclizumab, sirolimus, tacrolimus, etanercept, mycophenolate mofetil, etc.)

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Lantidra	
Approval Length	One Time Approval
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that patient has not achieved independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after previous infusion

AND

2 - Patient has not had more than three infusions of Lantidra in their lifetime*

Notes	*There are no data regarding the effectiveness or safety for patients r eceiving more than three infusions.

2 . Revision History

Date	Notes
11/27/2023	New Program

Prior Authorization Guideline

Guideline ID	GL-143555
Guideline Name	Leqembi (lecanemab-irmb)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Leqembi	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following:

- Diagnosis of mild cognitive impairment due to Alzheimer's disease

- Diagnosis of probable Alzheimer's disease dementia

AND

1.2 Submission of medical records (e.g., chart notes) confirming all of the following:

- Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0
- CDR Memory Box score of 0.5 or greater
- Mini-Mental State Examination score of 22 or greater

AND

2 - Submission of medical records (e.g., chart notes) confirming the presence of beta-amyloid protein deposition, as evidenced by one of the following:

2.1 Positive amyloid positron emission tomography (PET) scan

OR

2.2 Both of the following:

- Attestation that the patient does not have access to amyloid PET scanning
- Cerebrospinal fluid (CSF) biomarker or blood testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., Aβ42 level, Aβ42:Aβ40 ratio)

AND

3 - Provider attests that the patient's ApoE e4 carrier status is known prior to initiating treatment and a shared decision-making conversation regarding the results has been completed

AND

4 - Other differential diagnoses (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.) have been ruled out

AND

5 - Both of the following:

- Patient is not currently taking an anticoagulant (e.g., warfarin, dabigatran)
- Patient has no history of intracerebral hemorrhage (e.g., transient ischemic attack [TIA], stroke) within the previous year prior to initiating treatment

AND

6 - Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting

AND

7 - Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment

AND

8 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm)

AND

9 - One of the following:

9.1 Prescribed by a geriatrician or geriatric psychiatrist

OR

9.2 Prescribed by or in consultation with a neurologist

Product Name: Leqembi	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefitting from therapy as defined by both of the following:

1.1 Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following [2,3]:

- Patient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease
- Patient continues to have a diagnosis of probable Alzheimer's disease dementia

AND

1.2 Submission of medical records (e.g., chart notes) confirming all of the following [4-5]:

- Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0
- CDR Memory Box score of 0.5 or greater
- Mini-Mental State Examination score of 22 or greater

AND

2 - Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th and 7th infusion treatment to show one of the following:

2.1 Both of the following:

- Less than 10 new incident microhemorrhages
- 2 or less focal areas of superficial siderosis

OR

2.2 If 10 or more new incident microhemorrhages or greater than 2 focal areas of superficial siderosis are present, then both of the following:

- Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances)
- Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H)

AND

3 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm)

AND

4 - One of the following:

4.1 Prescribed by a geriatrician or geriatric psychiatrist

OR

4.2 Prescribed by or in consultation with a neurologist

2 . Definitions

Definition	Description
ARIA-E	Amyloid related imaging abnormality due to edema/effusion
ARIA-H	Amyloid related imaging abnormality due to micro hemorrhages and hemosiderin deposits

3 . Revision History

Date	Notes
2/28/2024	Updated specialist prescriber verbiage

Prior Authorization Guideline

Guideline ID	GL-129086
Guideline Name	Leqvio (inclisiran)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following:

1.1.1 Both of the following: [5]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.1.2 One of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following: [5]

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [2,4]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization

- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [4]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

- Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose
- Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by

one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [4]

AND

3 - One of the following:

3.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Patient is unable to maintain adherence to proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy

AND

5 - Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL for diagnosis of ASCVD [2]

- LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH [3]

AND

6 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

7 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting LDL-C reduction from baseline while on therapy

AND

2 - One of the following:

2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe) **AND** **3** - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

2 . Revision History

Date	Notes
9/1/2023	Update to account for 2022 ACC recommendations of a lower LDL th reshold of 55mg/dl for patients with ASCVD at very high risk.

Prior Authorization Guideline

Guideline ID	GL-99469
Guideline Name	Leucovorin- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Leucovorin tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Methotrexate toxicity prophylaxis

OR

1.2 Treatment of hematologic toxicity from folic acid antagonists (i.e., pyrimethamine toxicity treatment or trimethoprim toxicity treatment)

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-99575
Guideline Name	Lidocaine - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lidocaine 2% Gel	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Used with catheters or open mucus membrane areas.	

Product Name: Lidocaine 4 or 5% ointment	
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for Lidocaine 4 or 5% ointment should be denied. The plan's preferred product is Aspercreme with Lidocaine 4%.

2 . Revision History

Date	Notes
7/14/2021	Updated guideline

Prior Authorization Guideline

Guideline ID	GL-117420
Guideline Name	Lidoderm (lidocaine) 5% patches
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Brand Lidoderm patch, generic lidocaine patch	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

2 . Revision History

Date	Notes
11/29/2022	Updated approval duration

Prior Authorization Guideline

Guideline ID	GL-143794
Guideline Name	Likmez (metronidazole) oral suspension
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Likmez	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following diagnoses:

1.1.1 Trichomoniasis caused by Trichomonas vaginalis

OR

1.1.2 Acute intestinal amebiasis (amoebic dysentery) and amebic liver abscess

OR

1.1.3 Treatment of one the following serious infections caused by susceptible anaerobic bacteria:

- Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess, caused by Bacteroides species including the B. fragilis group (B. fragilis, B. ovatus, B. thetaiotaomicron, B. vulgatus), Parabacteroides distasonis, Clostridium species, Eubacterium species, Peptococcus species, and Peptostreptococcus species
- Skin and skin structure infections caused by Bacteroides species including the B. fragilis group, Clostridium species, Peptococcus species, Peptostreptococcus species, and Fusobacterium species
- Gynecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, caused by Bacteroides species including the B. fragilis group, Clostridium species, Peptococcus species, Peptostreptococcus species, and Fusobacterium species
- Bacterial septicemia caused by Bacteroides species including the B. fragilis group and Clostridium species
- Bone and joint infections, (as adjunctive therapy), caused by Bacteroides species including the B. fragilis group
- Central nervous system (CNS) infections, including meningitis and brain abscess, caused by Bacteroides species including the B. fragilis group
- Lower respiratory tract infections, including pneumonia, empyema, and lung abscess, caused by Bacteroides species including the B. fragilis group
- Endocarditis caused by Bacteroides species including the B. fragilis group

AND

1.2 One of the following:

1.2.1 Patient has a history of failure, contraindication, or intolerance to metronidazole tablets as evidenced by submission of medical records or claims history

OR

1.2.2 Patient has a swallowing disorder and cannot swallow solid oral dosage forms

2 . Revision History

Date	Notes
3/1/2024	Changed guideline name to reflect suspension formulation

Prior Authorization Guideline

Guideline ID	GL-123724
Guideline Name	Livmarli (maralixibat)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Livmarli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene

AND

2 - Documentation of ONE of the following:

- Total serum bile acid > 3x the upper limit of normal (ULN)
- Conjugated bilirubin > 1 mg/dL
- Fat soluble vitamin deficiency otherwise unexplainable
- Gammaglutamyl transpeptidase (GGT) > 3x ULN

AND

3 - Patient is experiencing moderate to severe cholestatic pruritus

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus:

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Patient is 3 months of age or older

AND

6 - Prescribed by or in consultation with a hepatologist

Product Name: Livmarli	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

2 . Revision History

Date	Notes
3/23/2023	Updated age criterion due to expanded age approval

Prior Authorization Guideline

Guideline ID	GL-113529
Guideline Name	Livtencity (maribavir)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/8/2022

1 . Criteria

Product Name: Livtencity	
Diagnosis	CMV infection/disease
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cytomegalovirus (CMV) infection/disease as confirmed by one of the following methods:

- quantitative polymerase chain reaction (qPCR)
- CMV pp65 antigenemia

AND

2 - Patient is a recipient of one of the following:

- Hematopoietic stem cell transplant
- Solid organ transplant

AND

3 - Trial and failure of a minimum 2 weeks duration, contraindication, or intolerance to one of the following therapies at an appropriately indicated dose:

- Intravenous (IV) ganciclovir
- Oral valganciclovir
- IV foscarnet
- IV cidofovir

AND

4 - Patient is 12 years of age or older

AND

5 - Patient weighs greater than or equal to 35kg

AND

6 - Prescribed by or in consultation with a provider who specializes in one of the following areas:

- Transplant
- Infectious Disease

2 . Revision History

Date	Notes
9/8/2022	Removed references and end note, no changes to clinical criteria.

Prior Authorization Guideline

Guideline ID	GL-135381
Guideline Name	Lodoco (colchicine)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Lodoco	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cardiovascular disease (CV)

AND

2 - Used for the secondary prevention of CV disease (e.g., very high-risk patients – see Table 1)

AND

3 - Patient is on guideline therapy management for multiple risk factors (e.g., dyslipidemia, hypertension, hyperglycemia) associated with CV disease

AND

4 - Submission of medical records (e.g., chart notes) or paid claims documenting trial and failure or intolerance to colchicine 0.6 mg tablets

Product Name: Lodoco	
Approval Length	6 months [C, 4]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduced risk of cardiovascular death, myocardial infarction, ischemia-driven coronoary revascularization)

2 . Background

Clinical Practice Guidelines

Table 1 [3]

Definition of Very High-Risk
History of multiple major ASCVD events
OR
One Major ASCVD event AND 2 or more high risk conditions

Major ASCVD Events
Recent ACS (within the past 12 months)
History of MI (other than recent ACS events listed above)
History of ischemic stroke
Symptomatic peripheral artery disease (history of claudication with ABI <0.85, or previous revascularization or amputation)
High-Risk Conditions
Age 65 or older
Familial hypercholesterolemia
History of previous coronary artery bypass graft surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
Diabetes
Hypertension
Chronic kidney disease (eGFR, 15–59 mL/min/1.73 m^2)
Current tobacco smoking
Persistently elevated LDL-C ≥100 mg/dL despite maximally tolerated statin therapy and ezetimibe
History of congestive heart failure

ABI indicates ankle brachial index;**ACS**, acute coronary syndrome; **ASCVD**, atherosclerotic cardiovascular disease; **CKD**, chronic kidney disease; **eGFR**, estimated glomerular filtration rate; **LDL-C,** low-density lipoprotein cholesterol; and **MI**, myocardial infarction.

3 . Revision History

Date	Notes

10/27/2023	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-112078
Guideline Name	Long-Acting Opioid Products - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/23/2022

1 . Criteria

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	PA REQUIRED for use of MAT and other Opioids (Reject 88)
Guideline Type	DUR
Approval Criteria **1** - Provider attests to notify the prescriber of the MAT therapy and the prescriber of the MAT therapy approves the concurrent opioid therapy.	

AND

2 - The days supply does not exceed 14 days for a surgical procedure.

AND

3 - The days supply does not exceed 5 days for all other requests.

AND

4 - There has not been a previous approval in the last 6 months.

Notes	Approval Length: 14 Days for surgical procedure, 5 Days for all other requests

Product Name: Generic morphine sulfate ER tablets, generic fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tablets	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

Notes	*Note: If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30 day authorization may be authorized

	one time for the requested drug/strength combination up to the reque sted quantity for transition to an alternative treatment.

Product Name: Generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, generic fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Duragesic	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

AND

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 The patient has a history of failure, contraindication or intolerance to a trial of at least THREE of the following (Document drugs and date of trials):*

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal**
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)
- FENTANYL PATCH 72-HOUR 12mcg, 25mcg, 50mcg, 75mcg & 100mcg

OR

2.1.2 Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care pain (Document date regimen was started)

AND

2.2 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment. **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5m cg/hr are n on-preferred. *Note: Claims history may be used in conjunction as doc umentation of drug, date, and duration of trial.

Product Name: Brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

AND

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 The patient has a history of failure, contraindication or intolerance to a trial of BOTH of the following (Document drugs and date of trials):*

- tramadol immediate release (IR)
- tramadol extended release tablets (non-biphasic release tablets)

OR

2.1.2 Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care pain (Document date regimen was started)

AND

2.2 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz ed one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: Claim s history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Generic morphine sulfate ER tablets, generic fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tablets

Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (Document drug(s) and date of trial)*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)*

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial)*

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz ed one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: Claim s history may be used in conjunction as documentation of drug, date, and duration of trial **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5m cg/hr, and 87.5 mcg/hr are non-preferred.

Product Name: Generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, generic fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Duragesic	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (Document drug(s) and date of trial)*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - The patient has a history of failure, contraindication or intolerance to at least THREE of the following (Document drugs and date of trials):)*

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal**
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)
- FENTANYL PATCH 72-HOUR 12mcg, 25mcg, 50mcg, 75mcg & 100mcg

AND

4 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

4.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial))*

AND

4.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial))*

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment. Additionall y **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5 m cg/hr are non-preferred. *Note: Claims history may be used in conjunc tion as documentation of drug, date, and duration of trial.

Product Name: Brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (Document drug(s) and date of trial)*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)*

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial)*

AND

3.3 The patient has a history of failure, contraindication or intolerance to BOTH of the following (Document drugs and date of trials):)*

- tramadol immediate release (IR)**
- tramadol extended release tablets (non-biphasic release tablets)**

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for tramadol extended release capsules or tramadol extend ed release biphasic release tablets and the member is currently taking th e requested long-acting opioid for at least 30 days and has met the m edical necessity authorization criteria requirements for treatment wi th an opioid, but has not tried the preferred alternatives a denial shoul d b e issued and a maximum 30-day authorization may be authorized

	one time for the requested drug/strength combination up to the reques ted quantity for transition to an alternative treatment. *Drug may requir e prior authorization *Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Generic morphine sulfate ER tablets, generic fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic

• Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time) • Pain management is required around the clock with a long-acting opioid	
Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment. **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5m cg/hr are n on-preferred.

Product Name: Generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, generic fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Duragesic	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- • The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment.**NOTE: F entanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5m cg/hr are non -preferred.

Product Name: Brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for tramadol extended release capsules or tramadol extend ed release biphasic release tablets and the member is currently taking th e requested long-acting opioid for at least 30 days and has met the

	m edical necessity authorization criteria requirements for treatment wi th an opioid, but has not tried the preferred alternatives a denial shoul d b e issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the reques ted quantity for transition to an alternative treatment.

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Criteria for Quantity Limit Reviews*
Guideline Type	Quantity Limit
Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (see Table 1 in the Background section)	
Notes	*Note: Authorization will be issued for • Cancer pain/hospice/end-of-life related pain: 12 months • All Tramadol ER requests: 12 months • Non-cancer pain/non-hospice/non-end-of-life related pain: 6 months

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Opioid Naïve (Not having filled an opioid in the past 120 days)*
Guideline Type	Morphine Milligram Equivalents (MME)** MME 50.00 exceeded; PA Required for dosage above 50 MEDD

Approval Criteria

1 - Opioid naïve members may receive greater than 50 morphine milligram equivalent (MME) based on the following:

1.1 If the request is for 50 MME to 90 MME, ONE of the following (NOTE: If the request exceeds 90 MME please skip this section and proceed to the Exceeding the 90 MME Cumulative Threshold Reviews section):

1.1.1 Diagnosis of ONE of the following:

- Cancer
- End of life pain (including hospice care)
- Palliative care
- Sickle cell anemia

OR

1.1.2 Patient is currently exceeding 50 MME and prescriber attests patient has been on a short-acting opioid in the past 120 days

OR

1.1.3 Document ALL of the following:

- The diagnosis associated with the need for pain management with opioid
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- The prescriber has acknowledged that they have completed an addiction risk and risk of overdose assessment
- Prescriber attests the member requires more than 50 MME per day to adequately control pain

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand

Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Cancer/Hospice/End-of-Life/Palliative Care/Skilled Nursing Facility/Traumatic Injury Related Pain*
Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalent (MME)** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Doses exceeding the cumulative morphine milligram equivalent (MME) of 90 milligrams will be approved up to the requested amount for ALL opioid products if the patient has one of the following conditions:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, including burns and excluding post-surgical procedure

AND

2 - Provider attests patient has been prescribed naloxone (may also be verified via paid pharmacy claims)

Notes	*Note: Authorization will be issued for 12 months for one of the above conditions. The authorization should be entered for an MME of 9999 s o as to prevent future disruptions in therapy if the patient's dose is inc r eased.

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Doses- Exceeding the Cumulative MME of 90 mg - Non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled Nursing Facility/Traumatic Injury Related Pain*

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalent (MME)** MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- if used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - BOTH of the following:

2.1 Patient has tried and failed non-opioid pain medication (document drug name and date of trial)

AND

2.2 Opioid medication doses of less than 90 morphine milligram equivalent (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

AND

3 - Provider attests patient has been prescribed naloxone (may also be verified via paid pharmacy claims)

Notes	*Note: If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose. **Note: Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain up to the current requested MME plus 90 MME.

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Non-cancer/non-hospice/non-end-of-life/non-palliative Nursing Facility/Traumatic Injury Related Pain* care/non-skilled
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalent (MME)** MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- if used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale) **AND** **3** - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement) **AND** **4** - Provider attests patient has been prescribed naloxone (may also be verified via paid pharmacy claims)	
Notes	*Note: If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose. **Note: Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain up to the current requested MME plus 90 MME.

2 . Background

Benefit/Coverage/Program Information

Table 1. CDC Recommended Long-Acting Opioid Maximum Milligram Morphine Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Fentanyl transdermal, mcg/hr	None
Hydrocodone	None

Methadone	None
Tapentadol	500mg ER
Oxymorphone	None
Oxycodone	Xtampza Only =288mg

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

Max MME is the maximum dose per day based on morphine milligram equivalents allowed without consultation or prescription by a pain specialist. Max MME is based upon the CDC guidelines and adjusted for currently available product strengths. Fentanyl is dosed in mcg/hr rather than mg/day

3 . Revision History

Date	Notes
8/22/2022	Added attestation criteria for naloxone rx requirement to 90 MME Exceeded sections.

Prior Authorization Guideline

Guideline ID	GL-99470
Guideline Name	Lonhala and Yupelri- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lonhala Magnair, Yupleri	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD

AND

2 - ONE of the following:

2.1 History of failure, contraindication or intolerance to Spiriva Handihaler (tiotropium)

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Handihaler) to control his/her COPD due to ONE of the following

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 Liters per minute)

AND

2.2.2 History of failure, contraindication or intolerance to ipratropium nebulized solution (generic Atrovent)

Product Name: Lonhala Magnair, Yupleri	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

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Prior Authorization Guideline

Guideline ID	GL-123414
Guideline Name	Lucemyra
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/18/2023

1 . Criteria

Product Name: Lucemyra	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For symptoms of abrupt opioid withdrawal

AND

2 - Opioids have been discontinued

AND

3 - BOTH of the following:

3.1 History of failure, contraindication, or intolerance to clonidine as verified by recent clonidine claims history in the past 180 days

AND

3.2 Lucemyra was initiated in the inpatient setting

AND

4 - Prescriber must verify patient has been screened for hepatic and renal impairment and that dosing is appropriate for the patient's degree of hepatic and renal function

AND

5 - Prescriber must verify patient's vital signs have been monitored and that the patient is capable of and has been instructed on self-monitoring for hypotension, orthostasis, bradycardia, and associated symptoms

AND

6 - Patient does not have severe coronary insufficiency, a recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia

AND

7 - Patient does not have congenital long QT syndrome

2 . Revision History

Date	Notes
3/17/2023	Removed note regarding approval duration

Prior Authorization Guideline

Guideline ID	GL-99471
Guideline Name	Lumizyme -Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lumizyme	
Diagnosis	Pompe disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency)	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-143521
Guideline Name	Lyfgenia (lovotibeglogene autotemcel)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Lyfgenia	
Approval Length	1 Time Authorization in Lifetime*
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of sickle cell disease (SCD)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has genotype βS/βS, βS/β0, or βS/β+

AND

3 - Patient is 12 years of age or older

AND

4 - Provider attests that patient is clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT)

AND

5 - Submission of medical records (e.g., chart notes) documenting patient has a history of at least 4 vaso-occlusive events (VOEs) in the past 24 months defined by one of following scenarios:

- an episode of acute pain with no medically determined cause other than vaso-occlusion, lasting more than 2 hours
- acute chest syndrome (ACS)
- acute hepatic sequestration
- acute splenic sequestration
- VOE requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving intravenous medications at each visit
- priapism requiring any level of medical attention

AND

6 - Submission of medical records (e.g., chart notes) confirming patient does not have more than two α-globin gene deletions

AND

7 - Submission of medical records (e.g., chart notes) confirming patient has obtained a negative test result for all of the following prior to cell collection:

- Hepatitis B virus (HBV)

- Hepatitis C virus (HCV)
- Human immunodeficiency virus (HIV)

AND

8 - Patient is able to provide an adequate number of cells to meet the minimum recommended dose of 3 x 10^6 CD34+ cells/kg

AND

9 - Patient will receive both of the following:

9.1 Full myeloablative conditioning with busulfan prior to treatment with Lyfgenia

AND

9.2 Anti-seizure prophylaxis with agents other than phenytoin prior to initiating busulfan conditioning

AND

10 - Prescriber attests that patient will discontinue disease modifying therapies for sickle cell disease (e.g., hydroxyurea, crizanlizumab, voxelotor) 8 weeks before the planned start of mobilization and conditioning

AND

11 - Prescribed by a provider at a SCD treatment center with expertise in gene therapy

AND

12 - Prescribed by one of the following:

- Hematologist/oncologist
- Specialist with expertise in the diagnosis and management of sickle cell disease

AND **13** - Both of the following: • Patient has never received any previous sickle cell gene therapy treatment in their lifetime (i.e., Casgevy, Lyfgenia) • Patient has never received prior allogeneic transplant	
Notes	*Per prescribing information, Lyfgenia is for one-time, single dose intr avenous use only.

2 . Revision History

Date	Notes
2/29/2024	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-105529
Guideline Name	Lyrica
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Lyrica	
Diagnosis	Seizure Disorder
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure disorder

AND

2 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

Product Name: Brand Lyrica	
Diagnosis	Neuropathic Pain Associated with Spinal Cord Injury
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuropathic pain associated with spinal cord injury

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Fibromyalgia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fibromyalgia

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Diabetic peripheral neuropathy (DPN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Post herpetic neuralgia (PHN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post herpetic neuralgia (PHN)

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Lyrica CR	
Diagnosis	Diabetic peripheral neuropathy (DPN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2 - History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800 milligrams daily for 4 weeks

AND

3 - History of failure, contraindication, or intolerance to treatment with ONE of the following:

- Tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks, or intolerance to a tricyclic antidepressant
- Serotonin and norepinephrine reuptake inhibitor (SNRI) antidepressant (i.e. duloxetine, venlafaxine)

AND

4 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

Product Name: Lyrica CR	
Diagnosis	Post herpetic neuralgia (PHN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post herpetic neuralgia (PHN)

AND

2 - History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800 milligrams daily for 4 weeks

AND

3 - History of failure, contraindication, or intolerance to a tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks

AND

4 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

2 . Revision History

Date	Notes
3/31/2022	Added step through generic for seizure indication. Updated all indicat ions to allow for any manufacturer of generic immediate-release caps ules or solution.

Prior Authorization Guideline

Guideline ID	GL-99473
Guideline Name	Lysteda
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Lysteda, generic tranexamic acid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cyclic heavy menstrual bleeding	

2 . Revision History

Date	Notes

3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-139358
Guideline Name	Lyvispah (baclofen granules), Ozobax/Ozobax DS (baclofen oral solution)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Lyvispah, Ozobax/DS, Brand Baclofen oral solution, generic baclofen oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure, or intolerance to baclofen tablets

OR

2 - Patient is unable to swallow oral tablets

2 . Revision History

Date	Notes
1/23/2024	added brand/generic baclofen oral solution as NP targets

Prior Authorization Guideline

Guideline ID	GL-114911
Guideline Name	Makena- AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/5/2022

1 . Criteria

Product Name: Brand Makena*, generic hydroxyprogesterone caproate*	
Guideline Type	Prior Authorization

Approval Criteria

1 - Current singleton pregnancy

AND

2 - History of a prior spontaneous preterm birth of a singleton pregnancy

AND **3** - Treatment is initiated between 16 weeks, 0 days of gestation and 20 weeks, 6 days of gestation **AND** **4** - Administration is to continue weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first **AND** **5** - Applies to generic hydroxyprogesterone caproate ONLY: patient has a history of failure, contraindication or intolerance to Brand Makena	
Notes	*NOTE: Approval duration is up to 21 weeks; approval duration should take into account gestation week when Makena will be started and only authorized up to week 37.

2 . Revision History

Date	Notes
10/4/2022	Updated gestational days for drug initiation to align w PI

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Prior Authorization Guideline

Guideline ID	GL-108625
Guideline Name	Marinol, Syndros
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Brand Marinol, Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to formulary generic dronabinol

OR

2.2 Patient is unable to swallow capsules

AND

3 - History of failure, contraindication, or intolerance to a 5HT-3 (5-hydroxytriptamine) receptor antagonist [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

AND

4 - History of failure, contraindication, or intolerance to ONE of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Generic Dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - History of failure, contraindication, or intolerance to a 5HT-3 (5-hydoxytriptamine) receptor antagonist [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

AND

3 - History of failure, contraindication, or intolerance to ONE of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol, Syndros	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

- Patient is less than 65 years of age
- History of failure, contraindication, or intolerance to Megace (megestrol)

AND

4 - ONE of the following:

4.1 History of failure, contraindication, or intolerance to formulary generic dronabinol

OR

4.2 Patient is unable to swallow capsules

Product Name: Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

- Patient is less than 65 years of age
- History of failure, contraindication, or intolerance to Megace (megestrol)

2 . Revision History

Date	Notes
6/23/2022	Removed cesamet from guideline name. Added Brand Marinol as NP target

Prior Authorization Guideline

Guideline ID	GL-99474
Guideline Name	Mepron
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Mepron, generic atovaquone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 The patient has a diagnosis (e.g. human immunodeficiency virus [HIV]) warranting Pneumocystis jirovecii pneumonia (PCP) infection prophylaxis

AND

1.1.2 The patient has a documented intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone

OR

1.2 BOTH of the following:

1.2.1 The patient has a diagnosis of mild to moderate pneumonia caused by P. jirovecii

AND

1.2.2 The patient has a documented intolerance, contraindication, or history of treatment failure to TMP-SMX

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-115355
Guideline Name	Metformin products - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/13/2022

1 . Criteria

Product Name: generic metformin 625 mg immediate-release tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of greater than or equal to 12 week trial of preferred metformin immediate-release products	

Product Name: generic metformin extended-release (generic for Fortamet and generic for Glumetza)	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR)

AND

1.2 ONE of the following:

1.2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.3 History of greater than or equal to 12 week trial of metformin immediate-release

AND

1.4 One of the following:

1.4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release, in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

Product Name: Brand Glumetza, Brand Fortamet	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR)

AND

1.2 ONE of the following:

1.2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.3 History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet)

AND

1.4 One of the following:

1.4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.5 History of greater than or equal to 12 week trial of metformin immediate-release

AND

1.6 One of the following:

1.6.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release, in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.6.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.7 Submission of article(s) published in the peer-reviewed medical literature showing that

the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR)

2 . Revision History

Date	Notes
10/13/2022	Removed Brand Glucophage XR as target

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Prior Authorization Guideline

Guideline ID	GL-133813
Guideline Name	Migranal
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Brand Migranal, Generic dihydroergotamine mesylate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - History of failure, contraindication, or intolerance to TWO preferred 5-HT1 (5-

hydroxytryptamine-1) receptor agonist (triptan) alternatives [eg, Imitrex (sumatriptan), Maxalt or Maxalt-MLT (rizatriptan)]

2 . Revision History

Date	Notes
9/26/2023	Removed QL section, no QLs in place.

Prior Authorization Guideline

Guideline ID	GL-108624
Guideline Name	Monurol
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Monurol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The provider has submitted labs showing the culture and sensitivity is positive for Monural and negative to Ciprofloxacin or Nitrofurantoin

OR

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Ciprofloxacin
- Nitrofurantoin

2 . Revision History

Date	Notes
6/23/2022	Added product name to criteria section, no change to criteria

Prior Authorization Guideline

Guideline ID	GL-99625
Guideline Name	Mozobil
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mozobil	
Approval Length	4 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Patients with non-Hodgkin's lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation
- Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation

AND **2** - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Zarxio (filgrastim)] **AND** **3** - Prescribed by, or in consultation with, a hematologist/oncologist	
Notes	*Authorization will be issued for 1 course of therapy (up to four days of therapy).

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-142072
Guideline Name	MS Agents - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: PREFERRED: Avonex, Brand Copaxone, generic dalfampridine, generic dimethyl fumarate capsules, generic fingolimod, Kesimpta, Ocrevus, Rebif, generic teriflunomide	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis (MS)	

Product Name: NON-PREFERRED: Brand Ampyra, Brand Aubagio, Bafiertam, Betaseron, Briumvi, Brand Gilenya, generic glatiramer acetate, Glatopa, Mavenclad, Mayzent, Plegridy,

Tascenso ODT, Brand Tecfidera capsules, Brand Tecfidera starter packs, generic dimethyl fumarate starter packs, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - One of the following:

2.1 Patient has a history of failure, contraindication, or intolerance to a trial of at least TWO of the preferred alternatives * (May require PA) (Verified via pharmacy paid claims or submission of medical records)

- Avonex
- Brand Copaxone
- generic dalfampridine
- generic dimethyl fumarate
- generic fingolimod
- Kesimpta
- Ocrevus
- Rebif
- generic teriflunomide
- Tysabri

OR

2.2 Patient is currently established on requested medication as documented by claims history or medical records (document drug, date, and duration of therapy)

Notes	* NOTE: Preferred Drug May Require PA

Product Name: PREFERRED: Avonex, Brand Copaxone, generic dalfampridine, generic dimethyl fumarate, generic fingolimod, Kesimpta, Ocrevus, Rebif, generic teriflunomide; NON-PREFERRED: Brand Ampyra, Brand Aubagio, Bafiertam, Betaseron, Briumvi, Brand Gilenya, generic glatiramer acetate, Glatopa, Mavenclad, Mayzent, Plegridy, Tascenso ODT, Brand

Tecfidera capsules, Brand Tecfidera starter packs, generic dimethyl fumarate starter packs, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

2 . Revision History

Date	Notes
2/28/2024	Removed Tysabri as target, now has drug-specific guideline.

Prior Authorization Guideline

Guideline ID	GL-99476
Guideline Name	Multaq
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Multaq	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of ONE of the following:

- Paroxysmal Atrial Fibrillation (AF)

- Persistent AF defined as AF less than 6 months duration

AND

1.1.2 ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.1.3 Patient does not have New York Heart Association (NYHA) Class IV heart failure

AND

1.1.4 Patient does not have symptomatic heart failure with recent decompensation requiring hospitalization

OR

1.2 For continuation of current therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

Guideline ID	GL-99626
Guideline Name	Myalept
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Congenital generalized lipodystrophy associated with leptin deficiency
- Acquired generalized lipodystrophy associated with leptin deficiency

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

AND

4 - Documentation demonstrates that patient has at least ONE of the following:

4.1 Diabetes mellitus or insulin resistance with persistent hyperglycemia (hemoglobin A1C greater than 7.0%) despite BOTH of the following:

- Dietary intervention
- Optimized insulin therapy at maximum tolerated doses

OR

4.2 Persistent hypertriglyceridemia (triglycerides greater than 250 milligrams per deciliter) despite BOTH of the following:

- Dietary intervention
- Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Myalept therapy

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-118559
Guideline Name	Myfembree (relugolix, estradiol, and norethindrone acetate), Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

AND

2 - Patient is premenopausal

AND

3 - One of the following:

3.1 History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

- Combination (estrogen/progestin) contraceptive
- Progestins
- Tranexamic acid

OR

3.2 Patient has had a previous interventional therapy to reduce bleeding

AND

4 - Treatment duration of therapy has not exceeded a total of 24 months

Product Name: Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.)

AND

2 - Treatment duration of therapy has not exceeded a total of 24 months

Product Name: Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - ONE of the following:

3.1 History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) contraceptive
- Progestins

OR

3.2 Patient has had surgical ablation to prevent recurrence

AND

4 - Treatment duration of Myfembree has not exceeded a total of 24 months

Product Name: Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain)

AND

2 - Treatment duration of Myfembree has not exceeded a total of 24 months

2 . Revision History

Date	Notes
12/19/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-99477
Guideline Name	Mytesi
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mytesi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) associated diarrhea	

2 . Revision History

Date	Notes

3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

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Prior Authorization Guideline

Guideline ID	GL-109903
Guideline Name	Nadolol
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name: Nadolol	
Diagnosis	PA required for patients 18 years of age or older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to 3 of the following:

- atenolol
- atenolol/chlorthalidone
- bisoprolol fumarate
- bisoprolol/hydrochlorothiazide
- carvedilol

- labetalol HCl
- metoprolol succinate
- metoprolol tartrate
- metoprolol/hydrochlorothiazide
- propranolol HCl
- propranolol/hydrochlorothiazide
- sotalol HCl

2 . Revision History

Date	Notes
7/28/2022	Updated indication verbiage, no change to clinical criteria.

Prior Authorization Guideline

Guideline ID	GL-99478
Guideline Name	Namzaric
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Namzaric	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 History of BOTH of the following:

1.1.1 Memantine (generic Namenda)

AND

1.1.2 Donepezil (generic Aricept)

AND

1.2 Patient is stabilized on 10mg of donepezil once daily

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-99627
Guideline Name	Natpara
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism

AND

1.2 25-hydroxy vitamin D level is above the lower limit of the normal laboratory reference range

AND

1.3 Patient is currently on active vitamin D (calcitriol) therapy

AND

1.4 Total serum calcium level (albumin corrected) is above 7.5 milligrams per deciliter

AND

2 - ONE of the following:

2.1 Patient is currently on calcium supplementation of 1-2 grams per day of elemental calcium in divided doses

OR

2.2 Patient has a contraindication to calcium supplementation

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 milligrams per deciliter)

AND

2 - Patient continues to take concomitant calcium supplementation that is sufficient to meet daily requirements

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-139372
Guideline Name	Nayzilam and Valtoco
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Nayzilam, Valtoco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epilepsy

AND

2 - Requested medication is being prescribed for the acute treatment of intermittent,

stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

Product Name: Nayzilam, Valtoco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Nayzilam, Valtoco	
Diagnosis	Requests Exceeding Quantity Limit
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician has provided rationale for needing to exceed the quantity limit of 2 boxes per 30 days

AND

2 - The requested dose is within the FDA (Food and Drug Administration) maximum dose per day

2 . Revision History

Date	Notes
1/23/2024	Remove diazepam gel requirement, removed step through Nayzilam for Valtoco. Combined PA Criteria for targets. Added QL criteria for re quests exceeding 2 boxes/ 30 days.

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Prior Authorization Guideline

Guideline ID	GL-125301
Guideline Name	Nexiclon XR (clonidine ER)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Nexiclon XR, Brand Clonidine ER (Nexiclon XR ABA)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used for treatment of hypertension

AND

2 - Trial and failure, contraindication, or intolerance to one of the following (verified via paid pharmacy claims or submitted chart notes):

- generic clonidine oral tablet
- generic clonidine topical patch

2 . Revision History

Date	Notes
5/25/2023	Added Nexiclon XR ABA as NP target. Updated dx criterion.

Prior Authorization Guideline

Guideline ID	GL-133979
Guideline Name	Nexletol, Nexlizet
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD)

AND

2 - ONE of the following:

2.1 Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e. atorvastatin 40-80 mg (milligrams), rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK [creatine kinase] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate- intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK [creatine kinase] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following LDL-C (low-density lipoprotein cholesterol) values while on maximally tolerated statin therapy within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - ONE of the following:

4.1 Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy

OR

4.2 Patient has a history of contraindication or intolerance to ezetimibe

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at maximally tolerated dose (unless patient has documented inability to take lipid-lowering therapy)

2 . Revision History

Date	Notes
9/28/2023	Removed documentation verbiage from statin contraindication (2.3.2) , changed "lipid lowering therapy" to "statin therapy" in criterion 3.

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Prior Authorization Guideline

Guideline ID	GL-99628
Guideline Name	Nityr- Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nityr	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary tyrosinemia type 1

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use Orfadin (nitisinone) capsules or suspension

Product Name: Nityr	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response (e.g. decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Nityr therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-99505
Guideline Name	Nocdurna
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nocdurna	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 - Patient wakes at least twice per night on a reoccurring basis to void

AND

3 - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months

AND

4 - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes [e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure]

AND

5 - Prescriber attests that the risks have been assessed and benefits outweigh the risks

Product Name: Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient has routine monitoring for serum sodium levels

AND

3 - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

2 . Revision History

Date	Notes
3/11/2021	Bulk copy from C&S Medicaid to Arizona Medicaid for 7/1 eff

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-104403
Guideline Name	Non-Preferred Drugs - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD) • Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/4/2022

1 . Criteria

Product Name: Non-Preferred Drugs	
Approval Length	12 months*
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

- If there are at least three preferred alternatives, history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to at least THREE preferred alternatives (Prior trials of formulary/preferred drug list (PDL)

alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)*

- If there are fewer than three preferred alternatives, the patient must have a history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the preferred products (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)*
- There are no preferred formulary alternatives for the requested drug*

AND

1.2 If the request is for a multi-source brand medication (i.e., MSC O) ONE of the following:

1.2.1 BOTH of the following:

- The brand is being requested because of an adverse reaction, allergy or sensitivity to the generic and the prescriber must attest to submitting the FDA MedWatch Form for allergic reactions to the medications.
- If there are generic product(s), the member has tried at least three (if available)

OR

1.2.2 ONE of the following:

- The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure).
- The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)
- Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.3 ONE of the following:

1.3.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication.

OR

1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- The requested drug must be used for a Food and Drug Administration (FDA)-approved indication.
- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.4 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program**

OR

2 - If the requested medication is a behavioral health medication, ONE of the following:

- The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days).
- The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge.

Notes	*Anti-infectives: Approve for the requested time frame, or if duration is not specified approve the request for 30 days. *Controlled Substances shall be approved for the requested time. If th ere is not a requested time period and it is not clear in the directions, approve for one time only. *Other medications: Approved for the requested time frame, or if durat ion is not specified, approve for 12 months.

	* For Non-Preferred Generics (i.e. MSC=Y) approvals: Please approv e at MSC=Y only. For preferred alternatives, use the non-preferred alternatives grid to id entify appropriate alternatives: https://uhgazure.sharepoint.com/sites/ CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID =0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B 6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&vie wid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2 Fsites%2FCST%2FCSDM%2FShared%20Documents%2FAZM%2FN F%20Alt%20Tables **Medications used solely for anti-obesity/weight l oss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfun ction, or sexual dysfunction purposes are NOT medically accepted ind ications and are NOT recognized as a covered benefit. Erectile dysfun ction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other t han ED.

2 . Revision History

Date	Notes
3/4/2022	Updated MSC criterion verbiage. Attached to Specialty formulary.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99528
Guideline Name	Non-Preferred Prenatal Vitamins
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Non-Preferred Prenatal Vitamins	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of failure, contraindication, or intolerance to ALL of the following preferred products:*	
Notes	*Please refer to the background table for the alternatives

2 . Background

Benefit/Coverage/Program Information

Preferred Products:

GPI-14	Product ID	Product Label	GPI-14 Description
78512000000315	73317105009	PRENATVITE TAB RX	*PRENATAL MULTIVITAMINS & MINERALS W/IRON & FA TAB 0.8 MG***
78512010000330	69543026790	PNV TABS TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	60258019309	PRENATABS RX TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070510	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070516	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070518	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	58657013390	THRIVITE RX TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	71186001924	VIL-RX TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	13811051690	VOL-TAB RX TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000352	13811002710	ELITE-OB TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 50-1.25 MG***
78512010000352	68025001010	OB COMPLETE TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 50-1.25 MG***
78512015000324	58657017001	M-NATAL PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	12830080001	M-VIT TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	70898022001	NEONATAL TAB COMPLTE	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	70898011501	NEONATAL PLS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***

78512015000324	75834005001	NIVA-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	00813931601	O-CAL FA TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	71399624609	ONE VITE TAB 1MG PLUS	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	39328010610	PRENATAL TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	39328010650	PRENATAL TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	63044015001	PRENATAL VIT TAB LOW IRON	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	63044015005	PRENATAL VIT TAB LOW IRON	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69543025810	PREPLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69543025850	PREPLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	67112010100	TRICARE TAB PRENATAL	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	17139080030	VITATHELY TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	13811051910	VOL-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	13811051950	VOL-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69367026701	WESTAB PLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000329	60258019201	TRINATE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 28-1 MG***
78512015000329	13811051410	VOL-NATE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 28-1 MG***
78512015000332	10267227001	CO-NATAL FA TAB 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***

78512015000332	73317828601	NEONATAL TAB COMPLETE	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000332	69543025910	PRETAB TAB 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000360	13811000710	TRINATAL RX TAB 1	*PRENATAL VIT W/ FE FUMARATE-FA TAB 60-1 MG***
78512015000360	51991056601	VINATE ONE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 60-1 MG***
78512015000366	58607081120	MYNATAL PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000366	58607010565	MYNATAL-Z TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000366	00642007912	VITAFOL-OB TAB 65-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000530	13811001490	COMPLETENATE CHW	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070710	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070716	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070718	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	60258019701	PRENATAL 19 CHW TAB	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	13925011701	SE-NATAL 19 CHW	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512016000130	13811004930	ULTIMATECARE CAP ONE	*PRENATAL VIT W/ FE CBN-FE ASP GLYC-FA-OMEGA 3 CAP 27-1MG***

78512018000116	23359010530	C-NATE DHA CAP 28-1-200	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	23359020030	RELNATE DHA CAP	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	69543037030	VIRT-NATE CAP DHA	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	64661008030	VIVA DHA CAP	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512022000320	69543024190	VIRT-PN TAB	*PRENATAL VIT W/ FE FUM-METHYLFOLATE-FA TAB 27-0.6-0.4 MG***
78512046000330	55495012501	ATABEX OB TAB 29-1MG	*PRENATAL VIT W/ FE BISGLYCINATE CHELATE-FA TAB 29-1 MG***
78512046000330	51991017801	VINATE II TAB	*PRENATAL VIT W/ FE BISGLYCINATE CHELATE-FA TAB 29-1 MG***
78512051000327	00178085890	CITRANATAL TA B RX	*PRENATAL W/O A W/ FE CARBONYL-FE GLUC-DSS-FA TAB 27-1MG***
78512058000150	52747062030	CONCEPT OB CAP	*PRENATAL W/O A W/FE FUM-FE POLY-FA CAP 130-92.4-1 MG***
78512058000150	13811053530	FOLIVANE-OB CAP	*PRENATAL W/O A W/FE FUM-FE POLY-FA CAP 130-92.4-1 MG***
78512060000325	51991015501	VINATE M TAB	*PRENATAL VIT W/ SEL-FE FUMARATE-FA TAB 27-1 MG***
78512070000330	42937070610	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	42937070616	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	42937070618	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	13925011601	SE-NATAL 19 TAB	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***

78512091000135	52747062130	CONCEPT DHA CAP	*PRENATAL W/FE FUM-FE POLY - FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	58657012130	DOTHELLE DHA CAP	*PRENATAL W/FE FUM-FE POLY - FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	13811053630	TARON-C DHA CAP	*PRENATAL W/FE FUM-FE POLY - FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	76439033130	VIRT-C DHA CAP	*PRENATAL W/FE FUM-FE POLY - FA-OMEGA 3 CAP 53.5-38-1 MG***
78516020006330	00642007630	VITAFOL-OB PAK +DHA	*PRENATAL MV W/FE FUM-FA TAB 65-1 MG & DHA CAP 250 MG PACK *
78516032000130	00642007030	VITAFOL-ONE CAP	*PRENATAL MV W/ FE POLYSAC CMPLX-FA-DHA CAP 29-1-200 MG***
78516032006325	00642007530	SELECT-OB+ PAK DHA	*PRENATAL MV W/FE POLY-FA CHW 29-1 MG & DHA CAP 250 MG PAK *

3 . Revision History

Date	Notes
5/18/2021	Arizona Medicaid 7.1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99629
Guideline Name	Northera
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Northera	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by ONE of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:

- At least a 20 millimeters of mercury (mm Hg) fall in systolic pressure
- At least a 10 mm Hg fall in diastolic pressure

AND

2 - nOH caused by ONE of the following:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)

AND

4 - The patient has tried at least TWO of the following non-pharmacologic interventions:

- Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]
- Raising the head of the bed 10 to 20 degrees
- Compression garments to the lower extremities or abdomen
- Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)
- Increased salt and water intake, if appropriate
- Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)

AND

5 - No previous diagnosis of supine hypertension

AND

6 - Prescribed by, or in consultation with, ONE of the following specialists:

- Cardiologist
- Neurologist

- Nephrologist

AND

7 - History of failure (after a trial of at least 30 days), contraindication or intolerance to BOTH of the following medications:

- Florinef (fludrocortisone)
- ProAmatine (midodrine)

Product Name: Northera	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Northera therapy

AND

2 - Physiological countermeasures for neurogenic orthostatic hypotension (nOH) continue to be employed

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99481
Guideline Name	Nourianz
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nourianz	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson’s disease

AND

2 - Used as adjunctive treatment to levodopa/carbidopa in patients experiencing “off” episodes

AND

3 - History of failure, contraindication, or intolerance to TWO anti-Parkinson’s disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Product Name: Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nourianz therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-141161
Guideline Name	Nucala (mepolizumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/7/2024

1 . Criteria

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following:

- Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months

OR

3.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications (verified via paid pharmacy claims):

4.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 6 years

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications (verified via paid pharmacy claims)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Submission of documentation (e.g., chart notes) confirming ONE of the following:

2.1 ALL of the following:

2.1.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:

2.1.1.1 TWO or more of the following symptoms for greater than or equal to 12 weeks duration:

- Mucopurulent discharge
- Nasal obstruction and congestion
- Decreased or absent sense of smell
- Facial pressure or pain

AND

2.1.1.2 ONE of the following:

- Evidence of inflammation on paranasal sinus examination or computed tomography (CT)
- Evidence of purulence coming from paranasal sinuses or ostiomeatal complex

AND

2.1.1.3 The presence of nasal polyps

AND

2.1.2 ONE of the following:

- Patient has required prior sino-nasal surgery
- Patient has required systemic corticosteroids in the previous 2 years

AND

2.1.3 Patient has been unable to obtain symptom relief after trial of ALL of the following agents/classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g. fluticasone, mometasone, triamcinolone, etc.)
- Antileukotriene agents (e.g. montelukast, zafirlukast, zileuton)

OR

2.2 ALL of the following:

2.2.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2.2.2 Patient is currently on Nucala therapy

AND

3 - Patient will receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids

AND

4 - Patient is NOT receiving Nucala in combination with another biologic medication [e.g., Xolair (omalizumab), Dupixent (dupilumab)]

AND

5 - Prescribed by or in consultation with one of the following:

- Otolaryngologist
- Allergist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to Nucala therapy

AND

2 - Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids

AND

3 - Patient is NOT receiving Nucala in combination with another biologic medication [e.g., Xolair (omalizumab), Dupixent (dupilumab)]

AND

4 - Prescribed by or in consultation with one of the following:

- Otolaryngologist
- Allergist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone)

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., increase in remission time)

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient has been diagnosed for at least 6 months

AND

3 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

4 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

6 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

7 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

2 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	200		400
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

3 . Revision History

Date	Notes
2/6/2024	Updated CRSwNP criteria to align with Dupixent criteria.

Prior Authorization Guideline

Guideline ID	GL-99482
Guideline Name	Nuedexta
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nuedexta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pseudobulbar affect (PBA)	

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99483
Guideline Name	Nuplazid
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson’s disease

AND

2 - Patient is currently experiencing hallucinations and delusions associated with Parkinson’s

disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson's disease diagnosis)

Product Name: Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Nuplazid therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-99522
Guideline Name	Nuzyra
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nuzyra	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 ALL of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

1.3.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics or antibiotic regimens:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Nuzyra	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 ALL of the following:

1.3.1 ONE of the following diagnoses:

1.3.1.1 BOTH of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

1.3.1.2 BOTH of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

AND

1.3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.3.3 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

OR

1.4 ALL of the following:

1.4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

1.4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

1.4.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

Product Name: Nuzyra	
Diagnosis	Off-Label Uses*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR **1.3** The medication is being prescribed by or in consultation with an infectious disease specialist.	
Notes	*Note: Authorization duration based on provider treatment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-123423
Guideline Name	OAB - Overactive Bladder Agents - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name: Brand Enablex, generic darifenacin ER, Brand Ditropan XL, Flavoxate, Gelnique, Gemtesa, Myrbetriq, generic oxybutynin 2.5mg IR tablet, generic oxybutynin oral solution, Oxytrol (Rx) patch, trospium IR/ER, Brand Vesicare, generic solifenacin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a history of failure, contraindication, or intolerance to a trial of THREE preferred products

- oxybutynin (generic Ditropan) 5 mg tablet
- oxybutynin ER (generic Ditropan XL)
- Brand Detrol
- Brand Detrol LA

- Brand Toviaz

AND

2 - For oxybutynin solution requests ONLY, patient must have intolerance to oxybutynin syrup

2 . Revision History

Date	Notes
3/17/2023	Added oxybutynin 2.5 mg tablet as NP drug. Specified preferred prer equisite option for all NPD is oxybutynin 5 mg IR tablet.

Prior Authorization Guideline

Guideline ID	GL-99630
Guideline Name	Ocaliva
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis (aka primary biliary cirrhosis)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid(e.g., Urso, ursodiol)

AND

2.1.2 Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

2.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

3 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Ocaliva therapy) while on Ocaliva therapy

AND

2 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-118556
Guideline Name	Octreotide Products - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - One of the following:

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

4.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea or flushing episodes

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea episodes

2 . Revision History

Date	Notes

12/19/2022	Removed NF criteria

Prior Authorization Guideline

Guideline ID	GL-136958
Guideline Name	Ojjaara (momelotinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of one of the following:

- Primary myelofibrosis

- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

1.2 Disease is intermediate or high risk

AND

1.3 Patient has anemia

Product Name: Ojjaara	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

2 . Revision History

Date	Notes
11/27/2023	New Program

Prior Authorization Guideline

Guideline ID	GL-123417
Guideline Name	Olumiant (baricitinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/18/2023

1 . Criteria

Product Name: Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine)

AND

4 - One of the following:

4.1 All of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Orencia (abatacept)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Olumiant therapy

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**	
Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. **Olumiant may be used with concomitant methotrexate, topical or inh aled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy **AND** **2** - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**	
Notes	**Olumiant may be used with concomitant methotrexate, topical or inh aled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized (Olumiant is only FDA approved when used for COVID 19 patients in an inpatient setting)

AND

3 - Patient requires one of the following:

- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation
- Extracorporeal membrane oxygenation (ECMO)

Notes	NOTE: Olumiant is only FDA approved when used for COVID 19 patients in an inpatient setting

Product Name: Olumiant	
Diagnosis	Alopecia Areata
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage for diagnosis of Alopecia Areata are not authorized and will not be approved

Notes	Approval Length: N/A - Requests for Alopecia Areata should not be approved. Deny as a benefit exclusion.

2 . Revision History

Date	Notes

3/17/2023	Added note to COVID 19 indication, no change to clinical criteria.

Prior Authorization Guideline

Guideline ID	GL-139347
Guideline Name	Omvoh (mirikizumab-mrkz)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Omvoh IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab)
- infliximab
- Xeljanz oral tablet (tofacitinib)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

6 - Will be administered as an intravenous induction dose

Product Name: Omvoh SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Omvoh SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

2 . Revision History

Date	Notes
1/23/2024	New program

Prior Authorization Guideline

Guideline ID	GL-139340
Guideline Name	Opfolda (miglustat)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Opfolda	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)

AND

1.2 Disease is confirmed by one of the following:

- Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay
- Molecular genetic testing confirms mutations in the GAA gene

AND

1.3 Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.)

AND

1.4 Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga)

AND

1.5 Patient weight is greater than or equal to 40 kg

AND

2 - Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)

Product Name: Opfolda	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in FVC, improvement in 6-minute walk distance [6MWD])

AND

2 - Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga)

AND

3 - Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)

2 . Revision History

Date	Notes
1/23/2024	New program

Prior Authorization Guideline

Guideline ID	GL-114493
Guideline Name	Opzelura (ruxolitinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	12 weeks [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - One of the following:

- Greater than or equal to 3% body surface area (BSA) involvement
- Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin)

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply of non-pharmacologic topical therapies (e.g., moisturizers) [2]

AND

6 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following:

- Medium or higher potency topical corticosteroid
- Elidel (pimecrolimus) cream*
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment*

AND

7 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

8 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

Notes	*Product may require step therapy

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in pruritus severity from baseline
- Improvement in quality of life from baseline

AND

2 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

3 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

Product Name: Opzelura	
Diagnosis	Nonsegmental Vitiligo
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage for diagnosis of nonsegmental vitiligo are not authorized and will not be approved

Notes	Approval Length: N/A - Requests for nonsegmental vitiligo should not be approved. Deny as a benefit exclusion.

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1

	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
9/26/2022	Added denial criteria for nonsegmental vitiligo

Prior Authorization Guideline

Guideline ID	GL-144627
Guideline Name	Oral Oncology Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD) • Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Oral Oncology Drugs: Akeega, Alecensa, Alunbrig, Augtyro, Avyakit, Balversa, Bosulif capsules, Bosulif tablets, Braftovi, Brukinsa, Cabometyx, Calquence, Caprelsa, Cometriq, Copiktra, Cotellic, Daurismo, Erivedge, Erleada, etoposide capsules, Farydak, Fruzaqla, Gavreto, Gilotrif, Hycamtin capsules, Ibrance, Iclusig, Idhifa, Imbruvica, Inlyta, Inrebic, Brand Iressa, generic gefitinib, Iwilfin, Jakafi, Jaypirca, Jylamvo, Kisqali, Kisqali-Femara Co-pack, Koselugo, Krazati, Lenvima, Lonsurf, Lorbrena, Lumakras, Lynparza, Lytgobi, Mekinist, Mektovi, Nerlynx, Brand Nexavar, generic sorafenib, Ninlaro, Nubeqa, Odomzo, Ogsiveo, Orserdu, Pemazyre, Piqray, Pomalyst, Qinlock, Retevmo, Rezlidhia, Rozlytrek, Rubraca, Rydapt, Stivarga, Sprycel, Tabrecta, Tafinlar, Tagrisso, Talzenna, Brand Tarceva, generic erlotinib, Tasigna, Tazverik, temozolomide capsules, Tepmetko, Tibsovo, Truqap, Tukysa, Turalio, Brand Tykerb, generic lapatinib, Vanflyta, Venclexta, Verzenio, Vitrakvi, Vizimpro, Votrient, Welireg, Xalkori, Xatmep, Brand Xeloda, generic capecitabine, Xospata, Xpovio, Xtandi, Yonsa, Zejula, Zelboraf, Zolinza, Zydelig, Zykadia, Brand Zytiga, generic abiraterone	
Diagnosis	Cancer Indications
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

Product Name: Oral Oncology Drugs: Brand Gleevec, generic imatinib, Brand Revlimid, generic lenalidomide	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

AND

2 - If the request is for the non-preferred Brand (Brand Gleevec or Brand Revlimid), patient must have tried and failed the preferred generic counterpart (generic imatinib or generic lenalidomide)

2 . Revision History

Date	Notes
3/27/2024	Retired drug specific guidelines for Gleevec and Revlimid. Added crit eria for targets Brand Gleevec, generic imatinib, Brand Revlimid, gen eric lenalidomide. Pt must step through preferred generic counterpart

Prior Authorization Guideline

Guideline ID	GL-136981
Guideline Name	Orencia (abatacept)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine])

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs):

- leflunomide (Arava)
- methotrexate (Rheumatrex/Trexall)

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - Patient is 2 years of age or older

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Orencia IV	
Diagnosis	Prophylaxis for Acute Graft versus Host Disease (aGVHD)
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of acute graft versus host disease (aGVHD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

AND

4 - Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT

AND

5 - Used in combination with both of the following:

- calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
- methotrexate

2 . Revision History

Date	Notes
11/28/2023	Added age criterion to PsA indication

Prior Authorization Guideline

Guideline ID	GL-128930
Guideline Name	Orfadin (nitisinone)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary tyrosinemia type 1	

2 . Revision History

Date	Notes

7/25/2023	Added GPI for nitisinone. Updated guideline name.

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Prior Authorization Guideline

Guideline ID	GL-99485
Guideline Name	Orilissa
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

4 - History of trial and failure, contraindication, or intolerance after a three month trial to ONE of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Product Name: Orilissa 150 mg	
Approval Length	6 months*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months**

Notes	*NOTE: Authorization for Orilissa 150 mg will be issued for 6 months up to a maximum of 24 months. **NOTE: Orilissa 150 mg once daily is indicated for a maximum of 24 months.

Product Name: Orilissa 200 mg	
Approval Length	6 months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

4 - History of trial and failure, contraindication, or intolerance after a three month trial to ONE of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND **5** - Prescribed by or in consultation with ONE of the following: • Obstetrics/Gynecologist (OB/GYN) • Reproductive endocrinologist	
Notes	*NOTE: Orilissa 200 mg twice daily is indicated for a maximum of 6 m onths.

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-116122
Guideline Name	Orkambi - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Orkambi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

AND

3 - Patient is 1 year of age or older

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Orkambi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Revision History

Date	Notes
10/27/2022	Updated age requirement, added new GPI

Prior Authorization Guideline

Guideline ID	GL-99486
Guideline Name	Osphena - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Osphena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause*

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following: • Estradiol vaginal cream • Estradiol vaginal tablet	
Notes	*Treatment of dyspareunia is a benefit exclusion.

Product Name: Osphena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-99724
Guideline Name	Otezla
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Behcet's Disease

AND

2 - Patient has active oral ulcers

AND

3 - History of failure, contraindication, or intolerance to one non-biologic (e.g., corticosteroids, colchicine) within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis, Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-120440
Guideline Name	Oxbryta (voxelotor)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Oxbryta	
Diagnosis	Sickle Cell Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is 4 years of age or older

AND

3 - One of the following:

3.1 Patient is currently receiving hydroxyurea therapy

OR

3.2 Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy

AND

4 - Patient has previously experienced 1 or more sickle cell-related vaso occlusive crises within the previous 12 months

AND

5 - Baseline hemoglobin (Hb) less than or equal to 10.5 grams per deciliter

AND

6 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

7 - Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

8 - Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Oxbryta	
Diagnosis	Sickle Cell Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least one of the following:

1.1 Increase in hemoglobin (Hb) by greater than or equal to 1 gram per deciliter from baseline

OR

1.2 Decrease in indirect bilirubin from baseline

OR

1.3 Decrease in percent reticulocyte count from baseline

OR

1.4 Patient has experienced a reduction in sickle cell-related vaso occlusive crises

AND

2 - Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

3 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND **4** - Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

2 . Revision History

Date	Notes
1/24/2023	Added new 300 mg tablet strength

Prior Authorization Guideline

Guideline ID	GL-99634
Guideline Name	Oxervate
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Oxervate	
Diagnosis	Neurotrophic keratitis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Stage 2 or 3 neurotrophic keratitis

AND

2 - History of failure to at least one OTC ocular artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99635
Guideline Name	Palforzia
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

1.1 A serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L (kilo units of allergen per liter)

AND

1.2 A meal wheal diameter that is at least 3mm (millimeters) larger than the negative control on skin-prick testing for peanut

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 BOTH of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Used in conjunction with a peanut-avoidant diet

AND

4 - Patient does not have one of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months
- Severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist or immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Palforzia therapy

AND

2 - Used in conjunction with a peanut-avoidant diet

AND

3 - Prescribed by or in consultation with an allergist or immunologist

AND

4 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-99636
Guideline Name	Palynziq
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - Physician attestation that the patient will not be receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride)

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles per liter

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles per liter

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

OR

2.3 BOTH of the following:

2.3.1 Patient is in initial titration/maintenance phase of dosing regimen (week 1-33)

AND

2.3.2 Patient will receive maximum labeled dosage of 40 milligrams (mg) once daily if response has not been obtained after 24 weeks of 20 mg once daily maintenance dosing

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride) [Prescription claim history that does not show any concomitant Kuvan claim within 60 days of reauthorization request may be used as documentation]

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99511
Guideline Name	Panretin
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Panretin	
Diagnosis	AIDS-related Kaposi's Sarcoma (KS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired immunodeficiency syndrome (AIDS)-related Kaposi's Sarcoma (KS)

AND

2 - Patient is not receiving systemic anti-KS treatment

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Panretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Panretin therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-105258
Guideline Name	Pediculicides - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Sklice, Brand Natroba, generic spinosad susp	
Diagnosis	Head lice
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of topical treatment of head lice infestations

AND

2 - For Brand Natroba requests ONLY: Trial and failure to generic spinosad suspension (verified via paid pharmacy claims or submission of medical records/chart notes)

2 . Revision History

Date	Notes
3/28/2022	Added step through generic for Brand Natroba.

Prior Authorization Guideline

Guideline ID	GL-120432
Guideline Name	Pedmark (sodium thiosulfate injection, solution)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Pedmark	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of solid tumors

AND

2 - Disease is BOTH of the following:

- Localized
- Non-Metastatic

AND

3 - Used for the prevention of ototoxicity due to cisplatin-based chemotherapy

AND

4 - Patient is 1 month of age or older

AND

5 - Prescribed by or in consultation with an oncologist

AND

6 - History of failure, or intolerance to generic sodium thiosulfate

2 . Revision History

Date	Notes
1/24/2023	New program

Prior Authorization Guideline

Guideline ID	GL-139338
Guideline Name	Pombiliti (cipaglucosidase alfa-atga)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Pombiliti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)

AND

1.2 Disease is confirmed by one of the following:

- Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay
- Molecular genetic testing confirms mutations in the GAA gene

AND

1.3 Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.)

AND

1.4 Medication is used in combination with Opfolda (miglustat)

AND

1.5 Patient weight is greater than or equal to 40 kg

AND

2 - Not to be used in combination with other miglustat products (i.e., Zavesca, Yargesa)

Product Name: Pombiliti	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in FVC, improvement in 6-minute walk distance [6MWD])

AND

2 - Medication is used in combination with Opfolda (miglustat)

AND

3 - Not to be used in combination with other miglustat products (i.e., Zavesca, Yargesa)

2 . Revision History

Date	Notes
1/23/2024	New program

Prior Authorization Guideline

Guideline ID	GL-133837
Guideline Name	Pradaxa Pellet Packs
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Pradaxa Pellet Packs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 8 years of age or younger

OR

1.2 ALL of the following:

1.2.1 Patient is between 9 and 12 years of age

AND

1.2.2 Requested medication is being used for one of the following diagnoses:

- Treatment of venous thromboembolic events (VTE) in patients who have been treated with a parenteral anticoagulant for at least 5 days
- To reduce the risk of recurrence of VTE in patients who have been previously treated

AND

1.2.3 One of the following:

1.2.3.1 Trial and failure, contraindication, or intolerance to Brand Pradaxa capsules (verified via paid pharmacy claims or submitted chart notes)

OR

1.2.3.2 Patient is unable to swallow oral tablets/capsules

2 . Revision History

Date	Notes
9/28/2023	New program

Prior Authorization Guideline

Guideline ID	GL-129084
Guideline Name	Praluent
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD) • Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following:	

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following*:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment low density lipoprotein cholesterol (LDL-C) of ONE of the following:

- Greater than 190 milligrams per deciliter (mg/dL)
- Greater than 155 mg/dL if less than 16 years of age

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C of ONE of the following:

- Greater than 190 mg/dL
- Greater than 155 mg/dL if less than 16 years of age

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low density lipoprotein), apoB (apolipoprotein B), or PCSK9 (proprotein convertase subtilisin/kexin type 9) gene*
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy [i.e. atorvastatin 40-80 milligrams (mg), rosuvastatin 20-40mg] and will continue to receive high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without creatine kinase [CK] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin

XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Used as an adjunct to a low-fat diet and exercise

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Notes	*Note: Results of prior genetic testing can be submitted as confirmation of diagnosis of HeFH.

Product Name: Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Product Name: Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 500 mg/dL (milligrams per deciliter)
- Treated LDL-C greater than 300 mg/dL

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL [low-density lipoprotein] apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

2 . Revision History

Date	Notes
9/1/2023	Update to account for 2022 ACC recommendations of a lower LDL th reshold of 55mg/dl for patients with ASCVD at very high risk.

Prior Authorization Guideline

Guideline ID	GL-99538
Guideline Name	Preferred Drugs- Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Diagnosis	Prior Authorization Administrative Guideline for Preferred Drugs Without Drug-Specific Criteria
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

1.3 If the patient is less than FDA minimum age, the prescriber attests they are aware of FDA labeling and feels the treatment with the requested product is medically necessary. (Document rationale for use)

Notes	Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexual dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99488
Guideline Name	Pretomanid
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Pretomanid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB)

OR

1.2 Treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

AND

2 - Pretomanid will be used in combination with bedaquiline and linezolid

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126921
Guideline Name	Prevymis
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD) • Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Prevymis	
Diagnosis	CMV Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT) Recipients
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Patient is a recipient of an allogeneic hematopoietic stem cell transplant
- Patient is cytomegalovirus (CMV) seropositive (R+)

AND

2 - Provider attests that Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

Product Name: Prevymis	
Diagnosis	CMV Prophylaxis in Kidney Transplant Recipients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Patient is a recipient of a kidney transplant
- Patient is cytomegalovirus (CMV) seronegative (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

AND

2 - Provider attests that Prevymis will be initiated between Day 0 and Day 7 post-transplantation; and is being prescribed as prophylaxis and not treatment of CMV infection

2 . Revision History

Date	Notes
6/26/2023	Added criteria for new kidney transplant indication. Added IV soln as target. Attached to SP formulary.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144823
Guideline Name	Primary Hyperoxaluria (PH1) Agents [Oxlumo (lumasiran), Rivfloza (nedosiran)]
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Oxlumo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2 - Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.1 One of the following:

- Elevated urinary oxalate excretion
- Elevated plasma oxalate concentration
- Spot urinary oxalate to creatinine molar ratio greater than normal for age

AND

2.2 One of the following:

- Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
- Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity

AND

3 - Patient has not received a liver transplant

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

Product Name: Rivfloza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2 - Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:

2.1 One of the following:

- Elevated urinary oxalate excretion
- Elevated plasma oxalate concentration
- Spot urinary oxalate to creatinine molar ratio greater than normal for age

AND

2.2 One of the following:

- Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
- Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity

AND

3 - Patient is 9 years of age or older

AND

4 - Patient has preserved kidney function (e.g., eGFR greater than or equal to 30mL/min/1.73m^2)

AND

5 - Patient has not received a liver transplant

AND

6 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

Product Name: Oxlumo, Rivfloza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration)

AND

2 - Patient has not received a liver transplant

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

2 . Revision History

Date	Notes
3/25/2024	Added Rivfloza as target, added criteria for Rivfloza. Updated guideli ne name.

Prior Authorization Guideline

Guideline ID	GL-99725
Guideline Name	Procysbi
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nephropathic cystinosis

AND

2 - Patient is 1 year of age or older

AND **3** - History of failure or intolerance to Cystagon (immediate-release cysteamine bitartrate)*

Notes	*Note: AZM generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Procysbi therapy	

2 . Revision History

Date	Notes
5/14/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99489
Guideline Name	Progesterone - Non-Oral
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Crinone, Endometrin	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)	

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-99490
Guideline Name	Provigil, Nuvigil
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Narcolepsy, Obstructive Sleep Apnea, Shift Work Disorder, Idiopathic Hypersomnia (off label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Narcolepsy
- Excessive sleepiness due to obstructive sleep apnea
- Excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)

- Idiopathic hypersomnia

AND

2 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Fatigue due to Multiple Sclerosis (off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is experiencing fatigue

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment-resistant depression, defined as BOTH of the following:

1.1 Diagnosis of ONE of the following:

- Major depressive disorder (MDD)
- Bipolar depression

AND

1.2 History of failure, contraindication, or intolerance to at least TWO antidepressants from different classes (e.g., SSRIs [selective serotonin reuptake inhibitors], SNRIs [serotonin-norepinephine reuptake inhibitors], bupropion)

AND

2 - Used as adjunctive therapy

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Used as adjunctive therapy

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-144658
Guideline Name	Pulmonary Arterial Hypertension (PAH) Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Product Name: PREFERRED DRUGS: Alyq, generic tadalafil, generic ambrisentan, generic bosentan, Liqrev, Orenitram, generic sildenafil tablets; NON-PREFERRED DRUGS: Brand Adcirca, Adempas, Brand Flolan, Brand Veletri, generic eprostenol, Brand Letairis, Opsumit, Brand Remodulin, generic trepostinil, Brand Revatio tablets, Brand Revatio suspension, generic sildenafil suspension. Brand Revatio injection, generic sildenafil injection, Tadliq suspension, Brand Tracleer tablet, Tracleer tablet for oral suspension, Tyvaso DPI, Tyvaso inhaltion solution, Uptravi, Ventavis	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - If the patient is requesting a non preferred product, patient has a history of failure, contraindication or intolerance to at least THREE of the following preferred alternatives* (NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Alyq or tadalafil
- generic ambrisentan
- generic bosentan
- Liqrev
- Orenitram
- generic sildenafil tablet (generic Revatio)

AND

6 - If the request is for Brand Adcirca, patient must have tried and failed generic tadalafil or Alyq

AND

7 - If the request is for Brand Revatio suspension or generic sildenafil suspension, ALL of the following:

- Patient is between 12 and 17 years of age
- Trial and failure or intolerance to oral tablet formulation
- Trial and failure or intolerance to Liqrev

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Product Name: PREFERRED DRUGS: Alyq, generic tadalafil, generic ambrisentan, generic bosentan, Liqrev, Orenitram, generic sildenafil tablets; NON-PREFERRED DRUGS: Brand Adcirca, Adempas, Brand Flolan, Brand Veletri, generic eprostenol, Brand Letairis, Opsumit, Brand Remodulin, generic trepostinil, Brand Revatio tablets, Brand Revatio suspension, generic sildenafil suspension. Brand Revatio injection, generic sildenafil injection, Tadliq suspension, Brand Tracleer tablet, Tracleer tablet for oral suspension, Tyvaso DPI, Tyvaso inhaltion solution, Uptravi, Ventavis	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/28/2024	Liqrev susp, generic orenitram, generic tadalafil (Adcirca) now Preferred. Brand Adcirca, Revatio/sildenafil suspension now NonPreferred

Prior Authorization Guideline

Guideline ID	GL-99638
Guideline Name	Pulmozyme
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Pulmozyme	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Cystic Fibrosis	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-107467
Guideline Name	Pyrukynd (mitapivat)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count)

AND

1.2 Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene:

- Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant
- Patients is not homozygous for the c.1436G>A (p.R479H) variant
- Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

1.3 Hemoglobin is less than or equal to 10g/dL

AND

1.4 Patient has symptomatic anemia or is transfusion dependent

AND

1.5 Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs)

AND

2 - Prescribed by or in consultation with a hematologist

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy [e.g., hemoglobin greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)] **AND** **2** - Prescribed by or in consultation with a hematologist	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 1-month authorization should be issued one time for Pyrukynd gradual therapy discontinuation.

2 . Revision History

Date	Notes
5/24/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-128982
Guideline Name	Qalsody (tofersen)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Qalsody	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis amyotrophic lateral sclerosis (ALS)

AND

1.2 Molecular genetic testing confirms mutation in the SOD1 gene

AND

1.3 Patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.)

AND

1.4 Patient has a percent (%) slow vital capacity (%SVC) greater than or equal to 50% at the start of treatment [A]

AND

1.5 Patient does not require permanent noninvasive ventilation or invasive ventilation

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

Product Name: Qalsody	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting slowed disease progression from baseline

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

2 . Endnotes

A. Those in the faster-progressing subgroup, which the primary and key secondary endpoints were formally tested, were required to have a slow vital capacity (SVC) greater than or equal to 65% of predicted value for sex, age, and height (from the sitting position) at screening. [2]

3 . Revision History

Date	Notes
7/26/2023	New program

Prior Authorization Guideline

Guideline ID	GL-129071
Guideline Name	Qutenza (capsaicin)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with postherpetic neuralgia (PHN)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of neuropathic pain associated with postherpetic neuralgia (PHN)

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial and failure, contraindication, or intolerance to ALL of the following:

- gabapentin
- pregabalin
- minimum 60-day trial of a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine)
- generic lidocaine 5% patch
- topical capsaicin cream

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial and failure, contraindication, or intolerance to ALL of the following:

- gabapentin
- pregabalin
- minimum 60-day trial of a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine)
- generic lidocaine 5% patch
- topical capsaicin cream
- duloxetine

Product Name: Qutenza	
Diagnosis	All indications
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - It has been at least 3 months since the last application/administration [B]

AND

2 - Patient experienced pain relief with a prior course of therapy

AND

3 - Patient is experiencing a return of neuropathic pain

2 . Revision History

Date	Notes
7/28/2023	New program

Prior Authorization Guideline

Guideline ID	GL-112929
Guideline Name	Radicava (edaravone)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Radicava IV, Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) per the revised EL Escorial and Airlie House diagnostic criteria

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient has scores greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment

AND

4 - Patient has a percent (%) forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

Product Name: Radicava IV, Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming positive clinical response to therapy (e.g., slowing in the decline of functional abilities)

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

2 . Revision History

Date	Notes
8/29/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-110773
Guideline Name	Ranolazine products
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/15/2022

1 . Criteria

Product Name: Brand Ranexa, generic ranolazine	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of ONE of the following standard anti-angina treatments:

1.1 One beta-blocker [e.g. Lopressor (metoprolol), Inderal (propranolol)]

OR

1.2 One calcium channel blocker [e.g. Procardia XL (nifedipine ER), Cardizem LA/Cardizem CD (diltiazemER)]

OR

1.3 One long acting nitrate therapy [e.g. Imdur (isosorbide mononitrate), Isordil (isosorbide dinitrate), Nitro-Time/Nitro-Dur/Nitro-Bid (nitroglycerin ER)]

AND

2 - For Brand Ranexa requests ONLY: Trial and failure to generic ranolazine (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Aspruzyo Sprinkle	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of ONE of the following standard anti-angina treatments:

1.1 One beta-blocker [e.g. Lopressor (metoprolol), Inderal (propranolol)]

OR

1.2 One calcium channel blocker [e.g. Procardia XL (nifedipine ER), Cardizem LA/Cardizem CD (diltiazemER)]

OR

1.3 One long acting nitrate therapy [e.g. Imdur (isosorbide mononitrate), Isordil (isosorbide dinitrate), Nitro-Time/Nitro-Dur/Nitro-Bid (nitroglycerin ER)]

AND

2 - One of the following:

2.1 Trial and failure to generic ranolazine (verified via paid pharmacy claims or submission of medical records/chart notes)

OR

2.2 One of the following:

- Patient is 8 years of age or younger
- Patient is unable to swallow the oral tablet (solid formulation) due to swallowing difficulties

2 . Revision History

Date	Notes
8/4/2022	Added Aspruzyo Sprinkle as target. Updated guideline name to Rano lazine Products

Prior Authorization Guideline

Guideline ID	GL-99523
Guideline Name	Rayos
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rayos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) or claims history documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate

AND

4 - History of failure, contraindication, or intolerance to TWO the following:

- Dexamethasone tablet, oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet, oral solution

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes

5/14/2021	Arizona Medicaid 7.1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-135344
Guideline Name	Reblozyl (luspatercept-aamt)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of beta thalassemia major

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden)

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of very low- to intermediate-risk myelodysplastic syndromes (MDS)

AND

2 - Patient does not have previous erythropoiesis stimulating agent use (ESA-naïve)

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels)

2 . Revision History

Date	Notes
10/23/2023	Added criteria for new indication of treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve).

Prior Authorization Guideline

Guideline ID	GL-102891
Guideline Name	Recorlev (levoketoconazole)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Recorlev	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Cushing's disease

AND

1.2 ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Recorlev	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy

Product Name: Recorlev	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recorlev will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Recorlev	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
2/3/2022	New Program (mirrors Isturisa PA criteria)

Prior Authorization Guideline

Guideline ID	GL-99492
Guideline Name	Rectiv
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rectiv	
Diagnosis	Pain Associated with Chronic Anal Fissures
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with chronic anal fissures

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

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Prior Authorization Guideline

Guideline ID	GL-102898
Guideline Name	Regranex
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/3/2022

1 . Criteria

Product Name: Regranex	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a lower extremity diabetic neuropathic ulcer	

2 . Revision History

Date	Notes

2/3/2022	Removed t/f Santyl prerequisite

Prior Authorization Guideline

Guideline ID	GL-120433
Guideline Name	Relyvrio (sodium phenylbutyrate and taurursodiol)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG)

AND

3 - Patient has had ALS symptoms for less than or equal to 18 months

AND

4 - Patient has a percent (%) forced vital capacity (% FVC) or slow vital capacity (% SVC) greater than or equal to 60% at the start of treatment

AND

5 - Patient does not require permanent noninvasive ventilation or invasive ventilation

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

Product Name: Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting slowed disease progression from baseline

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

2 . Revision History

Date	Notes
1/24/2023	New program

Prior Authorization Guideline

Guideline ID	GL-129083
Guideline Name	Repatha
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD) • Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Repatha	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH), Atherosclerotic cardiovascular disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following*:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 190 milligrams per deciliter (mg/dL) (greater than 155 mg/dL if less than 16 years of age)

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first degree relative less than 60 years of age
- Family history of myocardial infarction in second degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first or second degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first or second degree relative
- Family history of tendinous xanthomata and or arcus cornealis in first or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age)

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low-density lipoprotein), apoB (Apolipoprotein B), or PCSK9 (Proprotein convertase subtilisin/kexin type 9) gene*
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes

- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin [i.e.

simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate, and high intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate, and high intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Used as an adjunct to a low-fat diet and exercise

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HeFH .

Product Name: Repatha

Diagnosis	Heterozygous familial hypercholesterolemia (HeFH), Atherosclerotic cardiovascular disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 500 mg/dL (milligrams per deciliter)
- Treated LDL-C greater than 300 mg/dL

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL [low-density lipoprotein] apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist

- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is continuing a low-fat diet and exercise regimen

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

- Lipid Specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

2 . Revision History

Date	Notes
9/1/2023	Update to account for 2022 ACC recommendations of a lower LDL th reshold of 55mg/dl for patients with ASCVD at very high risk.

Prior Authorization Guideline

Guideline ID	GL-133811
Guideline Name	Respiratory Syncytial Virus (RSV) Vaccines
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Abrysvo, Arexvy	
Approval Length	14 days (1 injection per 2 years)
Guideline Type	Prior Authorization

Approval Criteria

1 - Vaccine is being used for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

AND

2 - Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy) in the previous 2 years

AND **3** - One of the following: **3.1** Age greater than or equal to 60 years* **OR** **3.2** Both of the following (applies to Abrysvo only): **3.2.1** Will be used for active immunization of pregnant individuals at 32 through 36 weeks gestational age **AND** **3.2.2** Will also be used for the prevention of severe LRTD caused by RSV in infants from birth through 6 months of age

Notes	*Prior authorization is not required for patients 60 years and older

2 . Revision History

Date	Notes
9/26/2023	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135318
Guideline Name	Retinal Vascular Disease Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Byooviz, Cimerli, Lucentis 0.5mg	
Diagnosis	Neovascular (wet) age-related macular degeneration (nAMD), Macular edema following retinal vein occlusion (RVO), Myopic choroidal neovascularization (mCNV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:	

- Neovascular (wet) age-related macular degeneration (nAMD)
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Cimerli, Lucentis 0.3mg	
Diagnosis	Diabetic macular edema (DME), Diabetic retinopathy (DR)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Beovu	
Diagnosis	Neovascular (wet) age-related macular degeneration (nAMD), Diabetic macular edema (DME)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Diabetic macular edema (DME)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Eylea

Diagnosis	Neovascular (wet) age-related macular degeneration (nAMD), Macular edema following retinal vein occlusion (RVO), Diabetic macular edema (DME), Diabetic retinopathy (DR)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Eylea HD	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Susvimo	
Diagnosis	Neovascular (wet) age-related macular degeneration (nAMD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of neovascular (wet) age-related macular degeneration (nAMD)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Vabysmo	
Diagnosis	Neovascular (wet) age-related macular degeneration (nAMD), Diabetic macular edema (DME)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Diabetic macular edema (DME)

AND

2 - Submission of medical records (e.g., chart notes) documenting treatment for a minimum of 90 days with compounded Avastin prepared by a 503(B) Outsourcing Facility has been ineffective in improvement of visual acuity, or not tolerated, or contraindicated (paid pharmacy claims may be used in conjunction with submitted documentation)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Susvimo, Vabysmo	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

Product Name: Eylea Injectable Vial	
Diagnosis	Retinopathy of Prematurity (ROP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of retinopathy of prematurity (ROP)

AND

2 - ONE of the following:

- Patient gestational age at birth less than or equal to 32 weeks
- Patient birth weight less than or equal to 1500 grams

AND

3 - Patient weight greater than 800 grams on day of treatment

AND

4 - Submission of medical records (e.g., chart notes) documenting retinopathy of prematurity (ROP) is present in at least one eye with one of the following classifications:

- ROP zone 1, stage 1 plus, 2 plus, 3, or 3 plus
- ROP zone 2, stage 2 plus or 3 plus
- AP - ROP (aggressive posterior ROP)

AND

5 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Eylea Injectable Vial	
Diagnosis	Retinopathy of Prematurity (RoP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by the absence of active ROP and unfavorable structural outcomes (e.g., retinal detachment, macular dragging, macular fold, retrolental opacity)

2 . Endnotes

A. Neovascular Age-Related Macular Degeneration (nAMD) may also be referred to as wet or exudative AMD. [1]
B. Congress established the 503(B) facilities to provide compounded pharmaceuticals for office use without a prescription. 503(B) Outsourcing Facilities are compounding pharmacies that must meet higher federal safety, sterility, and quality control standards. [5,6]

3 . Revision History

Date	Notes
10/23/2023	Added Eylea HD as target

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99639
Guideline Name	Revcovi - AZ
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe combined immunodeficiency disease (SCID)

AND

2 - Deficiency of adenosine deaminase is confirmed by one of the following:

- Deficiency or absence of adenosine deaminase (ADA) in plasma, lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus
- Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates compared to laboratory standard
- Decrease in ATP (Adenosine triphosphate) concentration in erythrocytes
- Molecular genetic confirmation of mutations in both alleles of the ADA1 gene
- Positive screening by T cell receptor excision circles (TRECs)

AND

3 - One of the following:

- Patient is not a suitable candidate for hematopoietic cell transplantation (HCT)
- Patient has failed HCT
- Patient is awaiting HCT

AND

4 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Revcovi (elapegademase) therapy

AND

2 - Patient has experienced a positive clinical response to therapy (e.g., normalization of plasma ADA activity, erythrocyte dATP levels, improvement of disease symptoms, etc.)

AND **3** - Dosing is in accordance with the United States Food and Drug Administration approved labeling

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99548
Guideline Name	Reyvow - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe migraine headaches with or without aura

AND

2 - Used for acute treatment of migraine

AND

3 - Patient is 18 years of age or older

AND

4 - Documentation of a one month trial resulting in therapeutic failure, contraindication, or intolerance to THREE ofthe following:

- naratriptan tablets
- rizatriptan tablets/ODT (oral disintegrating tablets)
- sumatriptan tablets/auto injection/cartridge or Imitrex nasal spray (Brand only)
- zolmitriptan tablets/ODT

AND

5 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain Specialist
- Headache Specialist*

AND

6 - Prescriber attests to ALL of the following:

- Patient has been informed the use of Reyvow may result in significant CNS impairment, and may impact the patient's ability to drive or operate machinery for 8 hours after each dose
- If used concurrently with a benzodiazepine or other drugs that could potentially cause central nervous system (CNS) depression, the prescriber has acknowledged that they have completed an assessment of increased risk for sedation and other cognitive and/or neuropsychiatric adverse events
- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

AND

7 - Both of the following:

7.1 One of the following

7.1.1 The patient must have a history of therapeutic failure, contraindication, or intolerance to THREE of the following:

- Amitriptyline (Elavil)**
- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)**
- Divalproex sodium [Depakote/Depakote ER (extended-release)]**
- Topiramate (Topamax)**
- VENLAFAXINE [EFFEXOR/EFFEXOR XR (EXTENDED-RELEASE)]**

OR

7.1.2 The patient must be currently treated with one of the following prophylactic therapies unless there is a contraindication or intolerance to ALL:

- Amitriptyline (Elavil)**
- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)**
- Divalproex sodium [Depakote/Depakote ER (extended-release)]**
- Topiramate (Topamax)**
- Venlafaxine [Effexor/Effexor XR (extended-release)]**

AND

7.2 Both of the Following

7.2.1 History of a therapeutic failure after 3 month trial, contraindication, or intolerance to two of the following biologic calcitonin gene-related peptide receptor (CGRP) antagonists for preventive treatment of migraine

- Ajovy (fremanezumab)
- Emgality (galcanezumab)
- Aimovig (erenumab)

AND

7.2.2 History of a therapeutic failure, contraindication, or intolerance to Ubrelvy

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS) **Drugs may require PA

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain Specialist
- Headache Specialist*

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS)

2 . Revision History

Date	Notes
7/13/2021	Updated Guideline

Prior Authorization Guideline

Guideline ID	GL-103329
Guideline Name	Rezurock (belumosudil)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease - Twice daily (BID) Therapy
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Patient is using medication concomitantly with one of the following:

- Strong CYP3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin)
- Proton pump inhibitor (e.g., omeprazole, pantoprazole, lansoprazole)

2 . Revision History

Date	Notes
2/3/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-133806
Guideline Name	Rezzayo (rezafungin)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Rezzayo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of candidemia or invasive candidiasis with limited or no alternative options

AND

2 - Patient is 18 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) or paid pharmacy claims confirming trial and failure, contraindication or intolerance to one of the following:

- generic caspofungin
- generic micafungin

2 . Revision History

Date	Notes
9/26/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99494
Guideline Name	Rhofade
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rhofade	
Diagnosis	Persistent erythema associated with rosacea
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of persistent erythema associated with rosacea

AND

2 - ONE of the following:

2.1 History of a 30 day or longer trial and failure of one of the following:

- metronidazole cream, gel, or lotion
- azelaic acid gel

OR

2.2 Contraindication or intolerance to both of the following:

- metronidazole cream, gel, or lotion
- azelaic acid gel

Product Name: Rhofade	
Diagnosis	Persistent erythema associated with rosacea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Rhofade therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-141171
Guideline Name	Rinvoq (upadacitinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/7/2024

1 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab) or Enbrel (etanercept)
- infliximab
- Orencia (abatacept)
- Xeljanz oral tablet (tofacitinib)

AND

4 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) oral tablet

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints)

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 Trial and failure, contraindication, or intolerance to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Xeljanz (tofacitinib) oral tablet

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - Submission of medical records documenting one of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting ALL of the following**:

5.1 History of failure, contraindication, or intolerance to the following topical therapies: (document drug, date of trial, and/or contraindication to medication)

- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

AND

5.2 Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting trial and failure of a minimum 12-week supply of Dupixent (dupilumab)

AND

5.3 Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting trial and failure of a minimum 12-week supply of Adbry (tralokinumab-ldrm)

AND

6 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). ** PA may be required. ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

3 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies (document drug, date, and duration of trial):

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab)
- infliximab
- Xeljanz oral tablet (tofacitinib)

AND

4 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) or paid claims history documenting BOTH of the following**:

3.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroids (e.g., prednisone)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Cimzia (certolizumab)
- Humira (adalimumab)
- infliximab

AND

4 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

- Reversal of high fecal output state

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Not used in combination with other JAK inhibitors, biological therapies for CD, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [5]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05

	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
2/6/2024	AD indication: Added step through Adbry. Updated verbiage for embe dded step criteria, no change to clinical intent.

Prior Authorization Guideline

Guideline ID	GL-116154
Guideline Name	Ryaltris
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Ryaltris	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure to both of the following as separate agents:

- generic mometasone nasal spray
- azelastine or olopatadine nasal spray

2 . Revision History

Date	Notes
10/27/2022	New program

Prior Authorization Guideline

Guideline ID	GL-133808
Guideline Name	Rystiggo (rozanolixizumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Rystiggo	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Submission of medical records (e.g., chart notes) documenting ONE of the following:

2.1 Both of the following:

2.1.1 Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

2.1.2 One of the following:

2.1.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) (May be verified via paid pharmacy claims)

OR

2.1.2.2 Both of the following:

2.1.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) (May be verified via paid pharmacy claims)

AND

2.1.2.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

OR

2.2 Both of the following:

2.2.1 Patient is anti-muscle-specific tyrosine kinase (MuSK) antibody positive

AND

2.2.2 One of the following:

2.2.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) (May be verified via paid pharmacy claims)

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) (May be verified via paid pharmacy claims)

AND

2.2.2.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)
- Rituximab

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Rystiggo	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

2 . Revision History

Date	Notes
9/26/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99642
Guideline Name	Samsca
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Samsca, generic tolvaptan	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of clinically significant euvolemic hyponatremia
- Diagnosis of clinically significant hypervolemic hyponatremia

AND

2 - Patient has not responded to fluid restriction

AND

3 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-137608
Guideline Name	Sedative Hypnotics - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name: Non-Preferred Drugs: Brand Ambien, Brand Ambien CR, Edluar, Brand Intermezzo, generic zolpidem SL tablets, Zolpimist, Belsomra, Dayvigo, estazolam, flurazepam, Brand Halcion, generic triazolam, Brand Lunesta, Quviviq, Brand Restoril, generic temazepam 7.5 mg and 22.5 mg capsules, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin, generic zaleplon	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of failure, contraindication, or intolerance to a trial of at least two of the following preferred agents:*	

- Eszopiclone (Generic Lunesta)
- Zolpidem/Zolpidem ER (Generic Ambien/Ambien CR)
- Temazepam 15/30mg capsules (Generic Restoril)

AND

2 - For generic ramelteon requests ONLY, patient must have tried and failed Brand Rozerem

Product Name: Brand Ambien, generic zolpidem, Brand Ambien CR, generic zolpidem ER, Edluar, Brand Intermezzo, generic zolpidem SL tablets, Zolpimist, Belsomra, Dayvigo, estazolam, flurazepam, Brand Halcion, generic triazolam, Brand Lunesta, generic eszopiclone, Quviviq, Brand Restoril, generic temazepam, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin, generic zaleplon	
Diagnosis	Reject 75: Greater than 1 hypnotic in 30 days
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used to adjust the dose of the drug

OR

2 - The requested medication will be used in place of the previously prescribed drug, and not in addition to it

OR

3 - The requested medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

4 - The physician attests they are aware of the multiple sedative hypnotics prescribed to the

patient and feels treatment with both medications is medically necessary (Document rationale for use)

Product Name: Brand Ambien, generic zolpidem, Brand Ambien CR, generic zolpidem ER, Edluar, Brand Intermezzo, generic zolpidem SL tablets, Zolpimist, Belsomra, Dayvigo, estazolam, flurazepam, Brand Halcion, generic triazolam, Brand Lunesta, generic eszopiclone, Quviviq, Brand Restoril, generic temazepam, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin, generic zaleplon	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

2 . Revision History

Date	Notes
12/11/2023	Removed generic zolpidem ER as target from NP section, added as prerequisite option with zolpidem IR formulation

Prior Authorization Guideline

Guideline ID	GL-99495
Guideline Name	Serevent Diskus - Arizona
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Serevent Diskus	
Diagnosis	Asthma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - Patient is 4 years of age or older

AND

3 - Patient is also receiving treatment with an inhaled corticosteroid

Product Name: Serevent Diskus	
Diagnosis	Exercise-Induced Bronchospasm
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of exercise-induced bronchospasm (EIB)

AND

2 - Being used for prevention

AND

3 - Patient is 4 years of age or older

Product Name: Serevent Diskus	
Diagnosis	Bronchospasm associated with chronic obstructive pulmonary disease (COPD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bronchospasm associated with chronic obstructive pulmonary disease (COPD)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

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Prior Authorization Guideline

Guideline ID	GL-139353
Guideline Name	SGLT-2 Inhibitors - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Brand Farxiga, generic dapagliflozin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

OR

1.2 One of the following:

- Diagnosis of chronic kidney disease (CKD)
- Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction
- Diagnosis of heart failure (NYHA class II-IV) with preserved ejection fraction

AND

2 - For generic dapagliflozin requests ONLY: History of failure, intolerance, or contraindication to Brand Farxiga

Product Name: Jardiance	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

- Patient is 10 years of age or older
- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

OR

1.2 Both of the following:

- Requested medication is being used to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

OR

1.3 Requested medication is being used for one of the following :

- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure
- To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.

Product Name: Invokana	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

Product Name: Invokamet, Invokamet XR, Segluromet, Steglatro, Synjardy, Synjardy XR, Trijardy XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

AND

2 - History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana

AND

3 - Patient is 10 years of age or older (applies to Synjardy requests ONLY)

Product Name: Brand Xigduo XR, generic dapagliflozin-metformin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

OR

1.2 One of the following:

- Diagnosis of chronic kidney disease (CKD)
- Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

2 - For generic dapagliflozin-metformin requests ONLY: History of failure, intolerance, or contraindication to Brand Xigduo XR

Product Name: Brenzavvy, Glyxambi, Qtern, Steglujan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of type 2 diabetes mellitus
- History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

AND

2 - History and failure, intolerance, or contraindication to ALL of the following:

- Janumet or Janumet XR
- Januvia
- Jentadueto or Jentadueto XR
- Kombiglyze XR
- Onglyza
- Tradjenta
- Trijardy XR

AND

3 - History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana

Product Name: Inpefa

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested medication is being used to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with one of the following:

- heart failure
- type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

AND

2 - History of failure, intolerance, or contraindication to Farxiga

2 . Revision History

Date	Notes
1/23/2024	Added generic Farxiga/Xigduo as NP

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Prior Authorization Guideline

Guideline ID	GL-116193
Guideline Name	Shingrix (zoster vaccine recombinant, adjuvanted)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Shingrix*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Vaccine is being used for prevention of herpes zoster (shingles)

AND

2 - Both of the following:

2.1 Patient is between 18 to 49 years of age **AND** **2.2** Patient is or will be at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy	
Notes	* Prior authorization is not required for patients 50 years of age and older.

2 . Revision History

Date	Notes
10/28/2022	New program

Prior Authorization Guideline

Guideline ID	GL-143791
Guideline Name	Short-Acting Opioid Products - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, Brand Tylenol/Codeine. generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Vicodin HP, Norco, Vicodin ES, Lorcet Plus, Lorcet, Lorcet HD, Brand Xodol, generic hydrocodone - ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Ro xicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, oxycodone-ibuprofen, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen -caffeine-dihydrocodeine, Trezix, Dvorah, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	PA REQUIRED for use of MAT and other Opioids (Reject 88)
Guideline Type	DUR

Approval Criteria

1 - Provider attests to notify the prescriber of the MAT therapy and the prescriber of the MAT therapy approves the concurrent opioid therapy.

AND

2 - The days supply does not exceed 14 days for a surgical procedure.

AND

3 - The days supply does not exceed 5 days for all other requests.

AND

4 - There has not been a previous approval in the last 6 months.

Notes	Approval Length: 14 Days for surgical procedure, 5 Days for all other r equests

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, Brand Tylenol/Codeine, Brand Fioricet/codeine, Brand Fiorinal/Codeine, Lortab, Vicodin HP, Norco, Vicodin ES, Lorcet Plus, Lorcet, Lorcet HD, Brand Xodol, Brand Dilaudid, , Brand Roxicodone, Brand Oxaydo, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, tramadol 25mg tablets, Synapryn, Brand Ultracet, generic tramadol-acetaminophen, Qdolo, Nucynta, Fortigan, generic levorphanol, generic acetaminophen -caffeine-dihydrocodeine, Trezix, Dvorah, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone- acetaminophen*	
Diagnosis	Non-Preferred Reviews **
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least FIVE preferred short -acting opioids **.

- hydromorphone (generic Dilaudid)
- meperidine
- morphine sulfate
- oxycodone (generic Roxicodone)
- tramadol (generic Ultram)
- oxycodone w/ acetaminophen (generic Percocet)
- oxycodone-ibuprofen
- acetaminophen w/ codeine
- butalbital-acetaminophen-caffeine w/ codeine (Generic Fioricet)
- butalbital-aspirin-caffeine w/cod (generic Fiorinal)
- hydrocodone-acetaminophen (generic Norco)
- hydrocodone-ibuprofen

Notes	*This section does NOT apply to cough and cold products.

Product Name: generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, generic butalbital-aspirin-caffeine-codeine, generic morphine, generic hydrocodone/acetaminophen, generic hydrocodone-ibuprofen, generic hydromorphone, generic oxycodone, generic oxycodone/acetaminophen, generic tramadol, generic meperidine	
Diagnosis	PA Required for > 2 Short Acting Opioids
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 The requested medication is being used to adjust the dose of the

OR

1.2 The requested medication will be used in place of the previously prescribed drug, and not in addition to it

OR

1.3 The requested medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

1.4 The physician attests they are aware of the multiple short-acting opioids prescribed to the patient and feels treatment with all medications is medically necessary (Document rationale for use)

Notes	*This section does NOT apply to cough and cold products. ** Authorization will be issued for the requested duration, not to exceed 12 months.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen

Diagnosis	Quantity Limit
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - The requested dose cannot be achieved by moving to a higher strength of the product

AND

2 - The requested dose is within FDA (Food and Drug Administration) approved maximum dose per day, where an FDA maximum dose per day exists (See table in background section)

Notes	*This section does NOT apply to cough and cold products.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen	
Diagnosis	Greater than 5 day supply requests for patients 18 years of age and older **
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following conditions or care instances:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, excluding post-surgical procedures
- Chronic conditions for which the provider has received PA approval
- Post-surgical procedures

Notes	Approvals are for 6 months for all of the above with the exception of p ost-surgical procedures which can be approved for a 14 day supply. A dults may obtain additional fills without PA if the refill is requested with in 60 days from the initial fill.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*

Diagnosis	Greater than 5 day supply requests for patients under 18 years of age**
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following conditions or care instances:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Children on opioid wean at time of hospital discharge
- Skilled nursing facility care
- Traumatic injury, excluding post-surgical procedures
- Chronic conditions for which the provider has received PA approval
- Post-surgical procedures

Notes	Approvals are for 6 months for all of the above with the exception of p ost-surgical procedures which can be approved for a 14 day supply. C hildren and adolescents may obtain additional fills without PA for 5 da ys supply unless the submitted PA supports a longer duration for use.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	Opioid Naïve (Not having filled an opioid in the past 120 days)*
Guideline Type	Morphine Milligram Equivalents (MME)** MME 50.00 exceeded; PA Required for dosage above 50 MEDD

Approval Criteria

1 - Opioid naïve members may receive greater than 50 morphine milligram equivalent (MME) based on the following:

1.1 If the request is for 50 MME to 90 MME, ONE of the following (NOTE: If the request exceeds 90 MME please skip this section and proceed to the Exceeding the 90 MME Cumulative Threshold Reviews section):

1.1.1 Diagnosis of ONE of the following:

- Cancer
- End of life pain (including hospice care)
- Palliative care
- Sickle cell anemia

OR

1.1.2 Patient is currently exceeding 50 MME and prescriber attests patient has been on a short-acting opioid in the past 120 days

OR

1.1.3 Document ALL of the following:

- The diagnosis associated with the need for pain management with opioid
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- The prescriber has acknowledged that they have completed an addiction risk and risk of overdose assessment
- Prescriber attests the member requires more than 50 MME per day to adequately control pain

Notes	*This section does NOT apply to cough and cold products. **Approval length for cancer, end of life, palliative care, or sickle cell pain will be i ssued for 12 months. All other approvals will be issued for one month.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand

Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	Cancer/Hospice/End of Life/ Palliative Care/Skilled Nursing Facility/Traumatic Injury Related Pain Exceeding the 90 MME Cumulative Threshold*
Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - ONE of the following conditions:

- Active oncology diagnosis
- Hospice
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, including burns and excluding post-surgical procedures

Notes	*This section does NOT apply to cough and cold products. ** The auth orization should be entered for an MME of 9999 so as to prevent futur e disruptions in therapy if the patient's dose is increased.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	Non-cancer/non-hospice/non-end of life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain Exceeding the 90 MME Cumulative Threshold*
Therapy Stage	Initial Authorization

Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - BOTH of the following:

- Patient has tried and failed non-opioid pain medication (document drug name and date of trial)
- • Opioid medication doses of less than 90 morphine milligram equivalent (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)***

Notes	*This section does NOT apply to cough and cold products. ** Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain related pain up to the current requested MME plus 90 MME. ***If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic

hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	Non-cancer/non-hospice/non-end of life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain Exceeding the 90 MME Cumulative Threshold*
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)***

Notes	*This section does NOT apply to cough and cold products. ** Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic inju

	ry related pain related pain up to the current requested MME plus 90 M ME. *** If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity au thorization criteria requirements, a denial should be issued and a maxi m um 30 -day authorization may be authorized one time for the reque sted MME dose.

2 . Background

Benefit/Coverage/Program Information

CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Hydrocodone	None
Tapentadol	600mg IR products
Oxymorphone	None
Oxycodone	None
Codeine	360mg
Pentazocine	None
Tramadol	400mg IR products
Meperidine	600mg
Butorphanol nasal	None
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day
Acetaminophen	4g/day
Aspirin	2080mg/day
Ibuprofen	3200mg/day

Benzhydrocodone**	None
Levorphanol	None
*Doses are not considered equianalgesic and table does not represent a dose conversion chart. **Morphine Milligram Equivalents is derived from the package insert.	

3 . Revision History

Date	Notes
3/1/2024	Added tramadol 25mg (NP) to 1st criteria box (MAT and opioids, rej 8 8).

Prior Authorization Guideline

Guideline ID	GL-99643
Guideline Name	Signifor
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 One of the following:

- Pituitary surgery has not been curative for the patient
- Patient is not a candidate for pituitary surgery

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Signifor therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99706
Guideline Name	Siliq- Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 Both of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.5 Patient is not receiving Siliq in combination with ONE of the following:

- Biologic Disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Siliq therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Siliq in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Siliq therapy

AND

2 - Patient is not receiving Siliq in combination with one of the following:

- Biologic Disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/11/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-142076
Guideline Name	Simponi, Simponi Aria (golimumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 One of the following:

1.2.1 Patient is receiving concurrent therapy with methotrexate (e.g., Rheumatrex, Trexall)

OR

1.2.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 History of failure, contraindication, or intolerance to all of the following:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Orencia (abatacept)
- Xeljanz (tofacitinib) oral tablet

AND

1.4 Prescribed by or in consultation with a rheumatologist

AND

1.5 For Simponi Aria Requests: Submission of medical records (e.g., chart notes) or paid claims documenting history of failure to self-administered Simponi (APPLIES TO REQUESTS FOR SIMPONI ARIA ONLY)

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Xeljanz (tofacitinib) oral tablet

AND

1.4 Prescribed by or in consultation with a rheumatologist

AND

1.5 For Simponi Aria Requests: Submission of medical records (e.g., chart notes) or paid claims documenting history of failure to self-administered Simponi (APPLIES TO REQUESTS FOR SIMPONI ARIA ONLY)

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis, Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) demonstrating positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following:

- Enbrel (etanercept) or Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) oral tablet

AND

1.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

AND

1.5 For Simponi Aria Requests: Submission of medical records (e.g., chart notes) or paid claims documenting history of failure to self-administered Simponi (APPLIES TO REQUESTS FOR SIMPONI ARIA ONLY)

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) demonstrating positive clinical response to therapy

AND

2 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting all of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis

AND

1.2 One of the following:

1.2.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

1.2.2 History of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)

- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab)
- Infliximab (Janssen manufacturer)
- Xeljanz (tofacitinib) oral tablet

AND

1.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) demonstrating positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of moderate to severely active PJIA

AND

2 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:

- methotrexate
- leflunomide

AND

3 - Submission of medical records (e.g., chart notes) documenting a history of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Enbrel (etanercept) or Humira (adalimumab)
- Orencia (abatacept)
- Xeljanz (tofacitinib) oral tablet

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) demonstrating positive clinical response to therapy as evidenced by at least one of the following:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
2/29/2024	Updated guideline name, added Simponi Aria as target where appropriate. Updated prerequisite agents, added criteria to direct to SC formulation.

Prior Authorization Guideline

Guideline ID	GL-99592
Guideline Name	Sivextro
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sivextro	
Diagnosis	Skin and Skin Structure Infections
Approval Length	6 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

OR

1.3 ALL of the following:

1.3.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

1.3.2 ONE of the following diagnoses:

1.3.2.1 BOTH of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

1.3.2.2 BOTH of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

AND

1.3.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.3.4 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline

- Clindamycin

OR

1.4 ALL of the following:

1.4.1 Diagnosis of acute bacterial skin and skin structure infection(including diabetic foot infections)

AND

1.4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

AND

1.4.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.4.4 History of failure, contraindication, or intolerance to TWO of the following antibiotics:

- Dicloxacillin
- A cephalosporin
- A tetracycline
- Amoxicillin/clavulanate
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Product Name: Sivextro	
Diagnosis	Off-Label Uses
Approval Length	60 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 The medication is being prescribed by or in consultation with an infectious disease specialist

AND

1.3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox), if culture and susceptibility confirm susceptibility.

2 . Revision History

Date	Notes
11/11/2021	Updated off-label approval duration to 60 days.

Prior Authorization Guideline

Guideline ID	GL-143858
Guideline Name	Skyclarys (omaveloxolone)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

- Diagnosis of Friedreich's ataxia
- Confirmed presence of a mutation in the frataxin (FXN) gene

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Neurogeneticist
- Physiatrist (Physical Medicine and Rehabilitation Specialist)

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., slowed disease progression, improvement in or stabilization of speech or swallowing, upper/lower limb coordination, upright stability)

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Neurogeneticist
- Physiatrist (Physical Medicine and Rehabilitation Specialist)

2 . Revision History

Date	Notes
3/19/2024	Updated criteria to remove mFARS scoring. Added examples of posit ive response to tx in reauth.

Prior Authorization Guideline

Guideline ID	GL-127066
Guideline Name	Skyrizi (risankizumab-rzaa)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 BOTH of the following:

1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Otezla (apremilast)

AND

2 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Skyrizi therapy **AND** **2** - Prescribed by or in consultation with a dermatologist	
Notes	**If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following: **1.1** Diagnosis of active psoriatic arthritis (PsA)	

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Enbrel (etanercept) or Humira (adalimumab)
- infliximab
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) oral tablet

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial **If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Skyrizi therapy

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	**If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of moderately to severely active Crohn's disease (CD)

AND

1.2 Trial and failure, contraindication, or intolerance to one of the following conventional therapies

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Cimzia (certolizumab)
- Humira (adalimumab)
- infliximab

AND

2 - Will be administered as an intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Skyrizi SC 180mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following

1.1 Diagnosis of moderately to severely active Crohn's disease (CD)

AND

1.2 History of failure, contraindication, or intolerance to one of the of the following conventional therapies (document drug, date, and duration of trial):*

- 6-mercaptopurine

- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following (document drug, date, and duration of trial):*

- Cimzia (certolizumab)
- Humira (adalimumab)
- infliximab

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **If patient meets criteria above, please approve at GPI-14**

Product Name: Skyrizi SC 180mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by at least one of the following:

• Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline • Reversal of high fecal output state **AND** **2** - Prescribed by or in consultation with a gastroenterologist
Notes: **If patient meets criteria above, please approve at GPI-14**

2 . Revision History

Date	Notes
6/26/2023	Updated t/f options

Prior Authorization Guideline

Guideline ID	GL-117546
Guideline Name	Skysona (elivaldogene autotemcel suspension)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Skysona	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of early, active cerebral adrenoleukodystrophy (CALD)

AND

2 - Submission of medical records (e.g., chart notes) documenting molecular genetic testing confirms mutation in the ABCD1 gene

AND

3 - Submission of medical records (e.g., chart notes) confirming ALL of the following:

- Patient has elevated very long chain fatty acid (VLCFA) levels
- Loes score between 0.5 and 9 (inclusive) based on brain MRI assessment [B, 4]
- Brain magnetic resonance imaging (MRI) utilizes Gadolinium enhancement (GdE +) and demonstrates demyelinating lesions [C, 5]
- Neurologic function score (NFS) less than or equal to 1

AND

4 - BOTH of the following:

- Patient is male sex
- Patient is 4 to 17 years of age

AND

5 - Patient is not eligible for an allogeneic hematopoietic stem cell transplant with an HLA-matched sibling donor

AND

6 - Submission of medical records (e.g., chart notes) confirming patient has obtained a negative test result for all of the following prior to cell collection:

- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2)
- Human immunodeficiency virus (HIV)

AND

7 - Patient does not have CALD secondary to head trauma

AND

8 - Discontinue prophylactic anti-retroviral medications (e.g., Truvada, Descovy) for at least one month prior to initiating medications for stem cell mobilization and until all cycles of apheresis are completed

AND

9 - Prescribed by a stem cell transplant physician from a qualified treatment center

AND

10 - Patient has never received Skysona treatment in their lifetime

2 . Revision History

Date	Notes
11/30/2022	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125910
Guideline Name	Sodium Oxybate Products (Lumryz, Xyrem, Xywav)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Lumryz, Brand Xyrem, Generic sodium oxybate, Xywav	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

AND

3 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Lumryz, Brand Xyrem, Generic sodium oxybate, Xywav	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Lumryz, Brand Xyrem, Generic sodium oxybate, Xywav	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Cataplexy is absent

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance of ALL of the following (MUST be verified via paid pharmacy claims or submission of medical records):

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 Armodafanil (Nuvigil)

AND

3.3 Sunosi (solriamfetol)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Lumryz, Brand Xyrem, Generic sodium oxybate, Xywav	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Xywav	
Diagnosis	Idiopathic Hypersomnia (IH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of idiopathic hypersomnia (IH) confirmed by ALL of the following:

1.1 Patient has experienced daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months

AND

1.2 A multiple sleep latency test (MSLT) documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤ 15 minutes

AND

1.3 The presence of at least one of the following:

- MSLT shows a mean sleep latency of ≤ 8 minutes
- Total 24-hour sleep time is ≥ 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log

AND

2 - Physician attestation to BOTH of the following:

2.1 Cataplexy is absent

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

AND

4 - History of failure, contraindication, or intolerance of ALL of the following (MUST be verified via paid pharmacy claims or submission of medical records):

- An amphetamine or methylphenidate based stimulant
- modafinil
- armodafinil

Product Name: Xywav	
Diagnosis	Idiopathic Hypersomnia (IH)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting reduction in symptoms of excessive daytime sleepiness associated with therapy

2 . Revision History

Date	Notes
5/30/2023	New program for sodium oxybate products

Prior Authorization Guideline

Guideline ID	GL-136960
Guideline Name	Sohonos (palovarotene)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Sohonos	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of Fibrodysplasia Ossificans Progressiva (FOP)

AND

1.2 Molecular genetic testing confirms mutation in the ACVR1 gene

AND

1.3 One of the following:

1.3.1 Both of the following:

- Patient is female
- Patient is 8 years of age or older

OR

1.3.2 Both of the following:

- Patient is male
- Patient is 10 years of age or older

AND

2 - Prescribed by or in consultation with one of the following:

- Geneticist
- Orthopedic physician
- Rheumatologist
- Endocrinologist

Product Name: Sohonos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that patient demonstrates positive clinical response to therapy (e.g., reduction of volume in new abnormal bone growth)

2 . Revision History

Date	Notes
12/1/2023	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99727
Guideline Name	Soliris- AZ
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Soliris	
Diagnosis	Atypical hemolytic uremic syndrome (aHUS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation supporting the diagnosis of atypical hemolytic uremic syndrome (aHUS) by ruling out BOTH of the following:

- Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS)*

- Thrombotic thrombocytopenia purpura (TTP) (e.g., rule out ADAMTS13 deficiency)

AND

2 - Laboratory results, signs, and/or symptoms attributed to aHUS (e.g., thrombocytopenia, microangiopathic hemolysis, thrombotic microangiopathy, acute renal failure, etc.)

AND

3 - Patient is treatment naïve with Soliris

AND

4 - Soliris is dosed according to the Food and Drug Administration (FDA) labeled dosing for aHUS

AND

5 - Prescribed by, or in consultation with, a hematologist or nephrologist

Product Name: Soliris	
Diagnosis	Atypical hemolytic uremic syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for atypical hemolytic uremic syndrome (aHUS)

AND

4 - Prescribed by, or in consultation with, a hematologist or nephrologist

Product Name: Soliris	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation supporting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) that includes BOTH of the following:

- Flow cytometry analysis confirming presence of PNH clones
- Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - Patient is treatment naïve with Soliris

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for PNH

AND

4 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name: Soliris	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Documentation demonstrating a positive clinical response from baseline (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in lactate dehydrogenase [LDH], increased reticulocyte count, etc.)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for paroxysmal nocturnal hemoglobinuria (PNH)

AND

4 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name: Soliris	
Diagnosis	Generalized myasthenia gravis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) confirming ALL of the following:

1.1 Patient has not failed a previous course of Soliris therapy

AND

1.2 Positive serologic test for anti-acetylcholine receptor (AChR) antibodies

AND

1.3 ONE of the following:

- History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation
- History of positive anticholinesterase test, e.g., edrophonium chloride test
- Patient has demonstrated improvement in myasthenia gravis (MG) signs on oral cholinesterase inhibitors, as assessed by the treating neurologist

AND

1.4 Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

AND

1.5 Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score greater than or equal to 6 at initiation of therapy

AND

2 - BOTH of the following:

2.1 History of failure of at least TWO immunosuppressive agents over the course of at least 12 months [e.g., azathioprine, methotrexate, cyclosporine, mycophenolate, etc.]

AND

2.2 Patient has required TWO or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least the previous 12 months without symptom control

AND

3 - Patient is currently on a stable therapeutic dose (at least 3 to 6 months) of immunosuppressive therapy

AND

4 - Soliris is initiated and titrated according to the United States Food and Drug Administration (FDA) labeled dosing for gMG: up to a maximum of 1200 milligrams every 2 weeks

AND

5 - Prescribed by, or in consultation, with a neurologist

Product Name: Soliris	
Diagnosis	Generalized myasthenia gravis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by ALL of the following:

- Improvement and/or maintenance of at least a 3 point improvement (reduction in score) in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score from pre-treatment baseline
- Reduction in signs and symptoms of myasthenia gravis
- Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Soliris (Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for generalized myasthenia gravis (gMG): up to a maximum of 1200 milligrams every 2 weeks

AND

4 - Prescribed by, or in consultation, with a neurologist

Product Name: Soliris	
Diagnosis	Neuromyelitis optica spectrum disorder (NMOSD)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirming ALL of the following:

1.1 Past medical history of ONE of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

1.2 Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies

AND

1.3 Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

2 - Patient has not failed a previous course of Soliris therapy

AND

3 - History of failure of, contraindication, or intolerance to rituximab (Rituxan, Ruxience, Truxima) therapy

AND

4 - One of the following:

4.1 History of at least two relapses during the previous 12 months prior to initiating Soliris

OR

4.2 History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris

AND

5 - Soliris is initiated and titrated according to the U.S. FDA labeled dosing for NMOSD, up to a maximum of 1200 mg every 2 weeks

AND

6 - Prescribed by, or in consultation with, a neurologist

AND

7 - Patient is NOT receiving Soliris in combination with one of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Anti-IL6 (interleukin 6) therapy [e.g., Actemra (tocilizumab)]

Product Name: Soliris	
Diagnosis	Neuromyelitis optica spectrum disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by BOTH of the following:

2.1 Reduction in the number and/or severity of relapses or signs and symptoms of neuromyelitis optica spectrum disorder (NMOSD)

AND

2.2 Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting Soliris. (Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure)

AND

3 - Soliris is dosed according to the U.S. FDA (Food and Drug Administration) labeled dosing for NMOSD: up to a maximum of 1200 mg every 2 weeks

AND

4 - Prescribed by, or in consultation with, a neurologist

AND

5 - Patient is not receiving Soliris in combination with one of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Anti-IL6 (interleukin 6) therapy [e.g., Actemra (tocilizumab)]

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-127060
Guideline Name	Somatuline Depot (lanreotide)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery
- Radiotherapy

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure, or intolerance to generic octreotide

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive

clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient does not show evidence of progressive disease while on therapy

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Oncologist

AND

4 - Trial and failure, or intolerance to generic octreotide

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

2 . Revision History

Date	Notes
6/26/2023	Added step through octreotide for acromegaly and carcinoid syndrome indications.

Prior Authorization Guideline

Guideline ID	GL-99644
Guideline Name	Somavert
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Somavert	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of acromegaly by ONE of the following:

- Serum GH (growth hormone) level greater than 1 ng/mL (nanograms per milliliter) after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum IGF-1 (Insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 One of the following:

1.2.1 Inadequate response to one of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 Not a candidate for all of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Inadequate response, intolerance, or contraindication to one of the following somatostatin analogs:

- Sandostatin (octreotide) or Sandostatin LAR
- Somatuline Depot (lanreotide)

OR

2 - Patient is currently on Somavert therapy for acromegaly

Product Name: Somavert	
Diagnosis	Acromegaly

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Somavert therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-99496
Guideline Name	Soriatane
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Soriatane, Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe psoriasis

AND

2 - Prescribed or recommended by a dermatologist

AND

3 - One of the following:

3.1 Patient is unresponsive to other therapies (e.g., topical corticosteroids, topical vitamin D analogs, tazarotene, methotrexate)

OR

3.2 Other therapies are contraindicated based on the patient's clinical condition

AND

4 - One of the following:

- Greater than or equal to 10% body surface area involvement
- Palmoplantar, facial, or genital involvement
- Severe scalp psoriasis

Product Name: Brand Soriatane, Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Soriatane therapy

AND

2 - Prescribed or recommended by a dermatologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-120601
Guideline Name	Sotyktu (deucravacitinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/27/2023

1 . Criteria

Product Name: Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g, chart notes) confirming diagnosis of moderate to severe plaque psoriasis

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following:

- At least 3% body surface area (BSA) involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Both of the following (verified via submission of records or paid pharmacy claims):

5.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Enbrel (etanercept)
- Humira (adalimumab)

AND

5.2 Trial and failure, contraindication, or intolerance to Otezla (apremilast)

AND

6 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine)

Product Name: Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming positive clinical response to therapy as evidenced by ONE of the following:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine)

2 . Revision History

Date	Notes
1/27/2023	Updated embedded step drug name to Otezla

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Prior Authorization Guideline

Guideline ID	GL-117539
Guideline Name	Spevigo (spesolimab-sbzo)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2022

1 . Criteria

Product Name: Spevigo	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of generalized pustular psoriasis (GPP)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has a moderate to severe GPP flare based on one of the following:

- Presence of fresh pustules (new appearance or worsening of pustules)
- At least 5% of body surface area (BSA) covered with erythema and the presence of pustules
- A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [B]
- GPPPGA pustulation sub score of at least 2 (mild)

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - Patient has not already received two infusions of Spevigo for a single flare

2 . Endnotes

A. Spevigo is administered as a single intravenous infusion. If GPP flare symptoms persist, an additional intravenous dose may be administered one week after the initial dose [1].
B. The total Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score ranges from 0 (clear) to 4 (severe) [1].

3 . Revision History

Date	Notes
11/30/2022	New program

Prior Authorization Guideline

Guideline ID	GL-99729
Guideline Name	Spinraza- Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Spinraza	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) type I, II, or III made by, or in consultation with, a neurologist with expertise in the diagnosis of SMA

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following:

- Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on use of non-invasive ventilation beyond use for naps and nightime sleep

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) or claims history of the baseline exam of one of the following exams (based on patient age and motor ability) to establish baseline motor ability:

- Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test (Non ambulatory)
- Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)

AND

6 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA

AND

7 - One of the following:

7.1 Patient has not previously received gene replacement therapy for the treatment of SMA

OR

7.2 One of the following:

7.2.1 Both of the following:

7.2.1.1 Patient recently received gene replacement therapy within the previous 6 months

AND

7.2.1.2 Patient has experienced a declination in clinical status since receipt of gene replacement therapy

OR

7.2.2 Both of the following:

7.2.2.1 Patient has previously received gene replacement therapy

AND

7.2.2.2 Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy

AND

8 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures

AND

9 - Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12 milligrams for each loading dose

Product Name: Spinraza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) type I, II, or III made by, or in consultation with, a neurologist with expertise in the diagnosis of SMA

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history confirming both of the following:

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following:

- Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on use of non-invasive ventilation beyond use for naps and nightime sleep

AND

5 - One of the following:

5.1 Patient has not previously received gene replacement therapy for the treatment of SMA

OR

5.2 Both of the following:

5.2.1 Patient has previously received gene replacement therapy

AND

5.2.2 Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy

AND

6 - Submission of medical records (e.g., chart notes, laboratory values) or claims history with the most recent results (less than 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by one of the following exams:

6.1 Both of the following for Hammersmith Infant Neurological Exam Part 2 (HINE-2) milestones:

6.1.1 One of the following:

- Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick

- Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

AND

6.1.2 One of the following:

- The patient exhibited improvement or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

6.2 One of the following for Hammersmith Functional Motor Scale Expanded (HFMSE):

- Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.3 One of the following for Upper Limb Module (ULM):

- Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.4 One of the following for Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND):

6.4.1 Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline

OR

6.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.4.3 Both of the following:

- Patient was prescribed Spinraza due to clinical declination after receipt of gene therapy
- Patients clinical status has stabilized after receipt of Spinraza therapy

AND

7 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA

AND

8 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures

AND

9 - Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12 milligrams every 4 months, starting 4 months after the last loading dose

2 . Revision History

Date	Notes
5/25/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-144742
Guideline Name	Spiriva (generic tiotropium) products
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/21/2024

1 . Criteria

Product Name: generic tiotropium bromide	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for generic tiotropium bromide (generic Spiriva Handihaler) should be denied. The plan's preferred products are Brand Spiriva Handihaler and Spiriva Respimat	
Notes	Note: Clinical Program: Brand Over Generic-Not Covered

2 . Revision History

Date	Notes

3/21/2024	Update guideline to add note that calls out brand is preferred

Prior Authorization Guideline

Guideline ID	GL-135541
Guideline Name	Spravato, ketamine - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Spravato, ketamine	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a confirmed diagnosis of major depressive disorder as defined by the DSM-V (Diagnostic and Statistical Manual of Mental Disorders) criteria and is treatment resistant

AND

2 - Patient is 18 years of age or older

AND

3 - Requested medication is prescribed by, or in consultation with, a psychiatric provider

AND

4 - ONE of the following:

4.1 Patient does not have an active substance use disorder (SUD)

OR

4.2 BOTH of the following:

- Patient has an active substance use disorder
- Patient is currently receiving treatment

AND

5 - ONE of the following:

5.1 Patient has experienced an inadequate response during the current depressive episode with BOTH of the following therapies:

5.1.1 Two antidepressants from at least two different classes [must include one of each AHCCCS (Arizona Health Care Cost Containment System) preferred agents: SSRI (selective serotonin reuptake inhibitor), SNRI (serotonin-norepinephrine reuptake inhibitor), or bupropion] having different mechanisms of action at the maximally tolerated labeled dose, each used for at least 4-6 weeks

AND

5.1.2 At least TWO augmentation therapies below for at least 4 weeks:

- SSRI or SNRI, and a second-generation antipsychotic used concomitantly (aripiprazole, quetiapine, risperidone, olanzapine)
- SSRI or SNRI, and lithium used concomitantly
- SSRI or SNRI, and liothyronine (T3) used concomitantly
- SSRI or SNRI, and mirtazapine
- SSRI and bupropion and buspirone

OR

5.2 Patient has active suicidal ideation and urgent symptom control is necessary

AND

6 - Requested medication is used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)

AND

7 - Requested medication is administered under the direct supervision of a healthcare provider

AND

8 - Provider is certified in the Spravato REMS (risk evaluation and mitigation strategy) program (Applies to Spravato requests ONLY)

AND

9 - Patient must be monitored by a health care provider for at least 2 hours after administration

Product Name: Spravato, ketamine	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has documented improvement or sustained improvement in depressive symptoms from baseline

AND

2 - Patient use of requested medication is in combination with an oral antidepressant

AND

3 - Patient administers requested medication under the direct supervision of a healthcare provider

AND

4 - Provider is certified in the Spravato REMS (risk evaluation and mitigation strategy) program (applies to Spravato requests ONLY)

AND

5 - Patient must continue to be monitored by a health care provider for at least 2 hours after administration

Product Name: Spravato, ketamine	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

Product Name: Spravato, ketamine	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5) criteria

AND

2 - Patient is experiencing an acute suicidal ideation or behavior

AND

3 - Patient is receiving newly initiated or optimized oral antidepressant

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program (applies to Spravato requests ONLY)

2 . Background

Benefit/Coverage/Program Information

HCPCS Codes

CODE	DESCRIPTION	LAY DESCRIPTION
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	A physician or an assistant under direct physician supervision infuses a hydration solution (prepackaged fluid and electrolytes) for 31 minutes to one hour through an intravenous catheter inserted by needle into a patient's vein or by infusion through an existing indwelling intravascular access catheter or port. Report 96361 for each additional hour beyond the first hour. Intravenous infusion for hydration lasting 30 minutes or less is not reported.
96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)	See 96360
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	A physician or an assistant under direct physician supervision injects or infuses a therapeutic, prophylactic (preventive), or diagnostic medication other than chemotherapy or other highly complex drugs or biologic agents via intravenous route. Infusions are administered through an intravenous catheter inserted by needle into a patient's vein or by injection or infusion through an existing indwelling intravascular access catheter or port. Report 96365 for the initial hour

		and 96366 for each additional hour. Report 96367 for each additional sequential infusion of a different substance or drug, up to one hour, and 96368 for each concurrent infusion of substances other than chemotherapy or other highly complex drugs or biologic agents.
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	See 96365
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	See 96365
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	A physician or an assistant under direct physician supervision injects or infuses a therapeutic, prophylactic (preventive), or diagnostic medication other than chemotherapy or other highly complex drugs or biologic agents via intravenous route. Infusions are administered through an intravenous catheter inserted by needle into a patient's vein or by injection or infusion through an existing indwelling intravascular access catheter or port. Report 96365 for the initial hour and 96366 for each additional hour. Report 96367 for each additional sequential infusion of a different substance or drug, up to one hour,

		and 96368 for each concurrent infusion of substances other than chemotherapy or other highly complex drugs or biologic agents.
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	The physician or an assistant under direct physician supervision administers a therapeutic, prophylactic, or diagnostic substance by subcutaneous or intramuscular injection (96372), intra-arterial injection (96373), or by push into an intravenous catheter or intravascular access device (96374 for a single or initial substance, 96375 for each additional sequential IV push of a new substance, and 96376 for each additional sequential IV push of the same substance after 30 minutes have elapsed). The push technique involves an infusion of less than 15 minutes. Code 96376 may be reported only by facilities.
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	See 96374
96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in	See 96374 Code 96376 may be reported only by facilities.

	addition to code for primary procedure)	
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion	

3 . Revision History

Date	Notes
10/27/2023	Added GPIs for injectable ketamine, updated criteria to reflect additio nal targets. Added HCPCS codes to background section

Prior Authorization Guideline

Guideline ID	GL-114494
Guideline Name	Stelara (ustekinumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Stelara SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 ONE of the following:

1.1.7.1 Requested medication is Stelara 45 mg (milligrams) per 0.5 mL (milliliter)

OR

1.1.7.2 BOTH of the following:

- Requested medication is Stelara 90 mg per 1 mL
- Patient's weight is greater than 100 kg (kilograms) (220 pounds)

AND

1.1.8 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

AND

2 - Patient is 6 years of age or older

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Stelara SC	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 ONE of the following

1.1.1.1 BOTH of the following:

- Requested medication is Stelara 45 mg (milligrams) per 0.5 mL (milliliter)
- Diagnosis of active psoriatic arthritis

OR

1.1.1.2 ALL of the following:

- Diagnosis of active psoriatic arthritis
- Diagnosis of co-existent moderate to severe plaque psoriasis

AND

1.1.2 Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.3 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to three of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

AND

2 - Patient is 6 years of age or older

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara SC	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Stelara SC, Stelara IV	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following:

2.1 Both of the following

2.1.1 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

AND

2.1.2 History of failure, contraindication or intolerance to Humira (adalimumab)

OR

2.2 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara SC, Stelara IV	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Both of the following

2.1.1 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

2.1.2 History of failure, contraindication or intolerance to Humira (adalimumab)

OR

2.2 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara SC, Stelara IV

Diagnosis	Crohn's Disease, Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
9/26/2022	Added age criterion for PsA and PsO. Updated product list.

Prior Authorization Guideline

Guideline ID	GL-99646
Guideline Name	Strensiq
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Strensiq	
Diagnosis	perinatal/infantile or juvenile-onset hypophosphatasia (HPP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on all of the following:

1.1.1 One of the following:

- Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)
- Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

AND

1.1.2 One of the following:

1.1.2.1 Both of the following:

- Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age-adjusted normal range
- Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

OR

1.1.2.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing*

AND

1.2 Prescribed by one of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

1.3 One of the following:

1.3.1 Both of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

OR

1.3.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

AND

1.4 One of the following:

1.4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

1.4.2 Both of the following:

- Patient is prescribed Strensiq 80 mg/0.8 mL vial
- Patient's weight is greater than or equal to 40 kg

AND

1.5 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering

Product Name: Strensiq	
Diagnosis	perinatal/infantile or juvenile-onset hypophosphatasia (HPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

AND

1.2 Prescribed by one of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

1.3 One of the following:

1.3.1 Both of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

OR

1.3.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

AND

1.4 One of the following:

1.4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

1.4.2 Both of the following

- Patient is prescribed Strensiq 80 mg/0.8 mL vials
- Patient's weight is greater than or equal to 40 kg

AND

1.5 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-121752
Guideline Name	Sublingual Immunotherapy (SLIT)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: All products	
Diagnosis	Patients 21 years of age and older
Approval Length	N/A - All requests for patients 21 years of age and older should be DENIED as benefit exclusion
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for patients 21 years of age and older are not covered	
Notes	Approval Length: N/A - All requests for patients 21 years of age and older should be denied as a benefit exclusion.

Product Name: Grastek	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to Timothy grass or cross-reactive grass pollens (eg, Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)
- in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Grastek	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Grastek therapy

Product Name: Oralair	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]
- in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

AND

3 - Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Oralair	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oralair therapy

Product Name: Ragwitek	
Diagnosis	Short ragweed pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to short ragweed pollen
- in vitro testing for pollen-specific IgE antibodies for short ragweed pollen

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Patient does not have unstable and/or uncontrolled asthma

AND

6 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Ragwitek	
Diagnosis	Short ragweed pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ragwitek therapy

Product Name: Odactra	
Diagnosis	House dust mite (HDM)-induced allergic rhinitis
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis.

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to licensed house dust mite allergen extracts
- in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites

AND

3 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

4 - Patient does not have unstable and/or uncontrolled asthma

AND

5 - Prescribed by or in consultation with a specialist in allergy and immunology

AND

6 - Patient is between 12 and 20 years of age*

Notes	*Odactra is not covered in patients 21 years of age or older

Product Name: Odactra	
Diagnosis	House dust mite (HDM)-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Odactra therapy **AND** **2** - Patient is between 12 and 20 years of age*	
Notes	*Odactra is not covered in patients 21 years of age or older

2 . Revision History

Date	Notes
2/27/2023	Added age criterion to Odactra initial and reauth

Prior Authorization Guideline

Guideline ID	GL-141063
Guideline Name	Sublocade, Brixadi - AZM
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/2/2024

1 . Criteria

Product Name: Sublocade	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has severe Opioid Use Disorder (OUD) as defined by the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) OUD Diagnostic Tool and has a demonstrated history of non-adherence to oral medications

AND

1.1.2 Patient is currently maintained on 8mg to 24mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection

AND

1.1.3 Patient will not receive supplemental oral, sublingual, or transmucosal buprenorphine for greater than 6 weeks after Sublocade therapy initiation

AND

1.1.4 Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program

AND

1.1.5 Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection

AND

1.1.6 Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: 300mg (milligrams) subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100mg or 300mg monthly

OR

1.2 Sublocade is being requested due to circumstances other than non-adherence to oral medications. Document circumstance(s).

Product Name: Sublocade	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician documentation that the patient has experienced a positive clinical response to buprenorphine extended-release therapy, as defined by the provider

AND

2 - Patient will not receive supplemental oral, sublingual, or transmucosal buprenorphine for greater than 6 weeks after Sublocade therapy initiation

AND

3 - Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program

AND

4 - Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection

AND

5 - Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: maintenance dose of 100mg (milligrams) or 300mg monthly

Product Name: Brixadi*	
Approval Length	N/A - Requests for Brixadi should not be approved
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed Sublocade	
Notes	*Requests for coverage of Brixadi are not authorized and will not be a pproved. Patient must use Sublocade. All Non preferred products will be denied for appeals process.

2 . Revision History

Date	Notes
2/2/2024	Updated verbiage for Sublocade criterion 1.2

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Prior Authorization Guideline

Guideline ID	GL-115713
Guideline Name	Suboxone - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/20/2022

1 . Criteria

Product Name: Generic buprenorphine-naloxone film	
Approval Length	N/A - Requests for generic buprenorphine hcl-naloxone film should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for generic buprenorphine-naloxone film are not authorized and will not be approved	
Notes	Approval Length: N/A - Requests for generic buprenorphine-naloxone film should not be approved. Patient need to use Brand Suboxone film or other preferred alternatives.

Product Name: Zubsolv, Bunavail	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a Diagnostic and Statistical Manual, Fifth Edition, Text Revision, (DSM-V-TR) diagnosis of opioid use disorder

AND

2 - The patient must have a reason or special circumstance that they cannot use the preferred products

- brand Suboxone Film
- buprenorphine (generic Subutex)
- buprenorphine HCl/naloxone Tab (Generic Suboxone Tab)
- naloxone
- naltrexone
- Narcan (naloxone)
- Sublocade (buprenorphine)
- Vivitrol (naltrexone microspheres)

Notes	*Up to 24 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the initial period.

Product Name: Zubsolv, Bunavail	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been prescribed a buprenorphine product for the purpose of opioid use disorder maintenance therapy

AND

2 - The patient must have a reason or special circumstance that they cannot use the preferred products

AND

3 - Patient must have tried Suboxone film or buprenorphine-naloxone ODT tablets

Notes	* Up to 16 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the reauthorization period.

Product Name: Brand suboxone, generic buprenorphine hcl-naloxone, buprenorphine/naloxone sublingual tablet, Zubsolv, Bunavail *	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician has provided rationale for needing to exceed the buprenorphine daily limit

AND

2 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

Notes	* This criteria applies to requests exceeding 24 mg of buprenorphine or equivalent

Product Name: Brand suboxone, generic buprenorphine hcl-naloxone, buprenorphine/naloxone sublingual tablet, Zubsolv, Bunavail *	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Quantity Limit

Approval Criteria **1** - Physician has provided rationale for needing to exceed the buprenorphine daily limit **AND** **2** - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation	
Notes	*This criteria applies to requests exceeding 16 mg of buprenorphine or equivalent

2 . Revision History

Date	Notes
10/20/2022	Removed reference to PDL

Prior Authorization Guideline

Guideline ID	GL-144103
Guideline Name	Sucraid
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/9/2024

1 . Criteria

Product Name: Sucraid	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital sucrase-isomaltase deficiency (CSID) as confirmed by one of the following:

1.1 Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides

OR

1.2 All of the following:

- Stool pH less than 6
- Negative lactose breath test
- Increase in breath hydrogen greater than 10 ppm (parts per million) when challenged with sucrose after fasting

AND

2 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

3 - Will be used with a sucrose-free, low starch diet

AND

4 - Provider attests that the requested medication will be obtained under compassionate use

Product Name: Sucraid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

2 - Will be used with a sucrose-free, low starch diet

AND

3 - Provider attests that the patient has achieved a clinically meaningful response while on Sucraid therapy, defined as at least a 50 percent reduction in all of the following:

- Symptoms of abdominal pain, cramps, bloating, gas, vomiting
- Number of stools per day
- Watery, loose stool consistency
- Number of symptomatic days

AND

4 - Provider attests that the requested medication will be obtained under compassionate use

2 . Revision History

Date	Notes
3/8/2024	Added criterion that the drug will be obtained under compassionate u se

Prior Authorization Guideline

Guideline ID	GL-121820
Guideline Name	Sunlenca (lenacapavir sodium)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Sunlenca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes) documenting all of the following:

1.1.1 Diagnosis of HIV-1 infection

AND

1.1.2 Both of the following:

1.1.2.1 Patient is heavily treatment-experienced with multidrug resistance as confirmed by a resistance assay

AND

1.1.2.2 Patient is failing their current antiretroviral regimen due to one of the following:

- Resistance
- Intolerance
- Safety considerations

AND

1.1.3 Patient is currently taking, or will be prescribed, an active and optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

2 . Revision History

Date	Notes
2/28/2023	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99524
Guideline Name	Sunosi
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

OR

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

AND

2 - Physician attestation to the following:

- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance to BOTH of the following:

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 Armodafinil

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with ONE of the following:

1.1 Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study

OR

1.2 BOTH of the following:

1.2.1 Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study

AND

1.2.2 ONE or more of the following sign/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by bed partner or other observer
- Observed apnea

AND

2 - BOTH of the following:

2.1 Standard treatments for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - History of failure, contraindication, or intolerance to armodafinil

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g. continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP])

2 . Revision History

Date	Notes
5/27/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99767
Guideline Name	Sutent
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of failure, contraindication, or intolerance to Gleevec (imatinib)

Product Name: Sutent	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 Diagnosis of Stage IV disease

OR

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

AND

2.3.2 Patient has a high risk of recurrence following nephrectomy

Product Name: Sutent

Diagnosis	Islet Cell Tumor / Progressive Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of islet cell tumor / progressive pancreatic neuroendocrine tumors (pNET)

AND

2 - Disease is ONE of the following:

- Unresectable, locally advanced
- Metastatic

Product Name: Sutent	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor / hemangiopericytoma

Product Name: Sutent	
Diagnosis	Thyroid Carcinoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Patient has progressive disease
- Patient has symptomatic metastatic disease

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Sutent	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name: Sutent	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of surgically inaccessible meningiomas

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Product Name: Sutent	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

AND

2 - Used as second-line following a failure, contraindication, or intolerance to a first-line chemotherapy regimen (e.g., carboplatin/paclitaxel)

Product Name: Sutent

Diagnosis	Gastrointestinal Stromal Tumor (GIST), Renal Cell Carcinoma (RCC), Islet Cell Tumor / Progressive Pancreatic Neuroendocrine Tumors (pNET), Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Product Name: Sutent	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Sutent will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Sutent	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sutent therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-124881
Guideline Name	Syfovre (pegcetacoplan)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Syfovre	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) as confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)

- Fluorescein angiography

AND

2 - GA is not secondary to any other conditions (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Syfovre	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

2 . Revision History

Date	Notes
4/20/2023	New Program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99649
Guideline Name	Symdeko
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory result documenting ONE of the following:

2.1 The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

OR

2.2 The patient has at least ONE mutation in the CFTR gene that is responsive to Symdeko (See Table in Background Section)

AND

3 - The patient is greater than or equal to 6 years of age

AND

4 - Prescribed by or in consultation with a specialist affiliated with a CF care center

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Symdeko therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Background

Benefit/Coverage/Program Information

Table 1 CFTR Gene Mutations

A1067T	D1270N	F1052V	R1070W	S945L	3272-26A→G
A455E	D579G	F1074L	R117C	S977F	3849+10kbC→T
D110E	E193K	K1060T	R347H		711+3A→G
D110H	E56K	L206W	R352Q		2789+5G→A
D1152H	E831X	P67L	R74W		

3 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99499
Guideline Name	Symlin
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Symlin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have ONE of the following diagnoses:

- Type 1 diabetes
- Type 2 diabetes

AND

2 - Concurrent use of insulin therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-117156
Guideline Name	Synagis
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/21/2022

Note:

PLEASE NOTE: PA IS NOT REQUIRED FOR CHILDREN UNDER 2 YEARS OF AGE

1 . Criteria

Product Name: Synagis*	
Diagnosis	Prematurity
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is an infant born before 29 weeks, 0 days gestation

AND

1.2 Patient is less than 12 months of age at the start of RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

• Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Chronic Lung Disease (CLD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following for patients age 0 to less than 12 months:

1.1.1 The patient is a preterm infant defined as gestational age less than 32 weeks, 0 days

AND

1.1.2 Patient has developed chronic lung disease (CLD) of prematurity

AND

1.1.3 There was a requirement for greater than 21% oxygen for at least the first 28 days after birth

OR

1.2 ALL of the following for patients age greater than or equal to 12 months to less than 24 months:

1.2.1 The patient was born at less than 32 weeks, 0 days gestation

AND

1.2.2 The patient required at least 28 days of oxygen after birth

AND

1.2.3 The patient continues to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital Heart Disease (CHD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following for patients age 0 to less than 12 months:

1.1.1 Patient has hemodynamically significant congenital heart disease (CHD) including ONE of the following:

- Acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Moderate to severe pulmonary hypertension

- Documentation that decisions regarding prophylaxis for infants with cyanotic heart defects were made in consultation with a pediatric cardiologist

OR

1.1.2 The patient is undergoing cardiac transplantation during the RSV “season”

OR

1.2 BOTH of the following:

1.2.1 The patient is greater than or equal to 12 months to less than 24 months of age:

AND

1.2.2 ONE of the following:

- After cardiac bypass
- At the conclusion of extracorporeal membrane oxygenation
- The patient is undergoing cardiac transplantation during the RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital abnormalities of the airway or neuromuscular disease
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is age 0 to less than 12 months

AND

1.2 Patient has ONE of the following:

- Neuromuscular disease
- A congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)

• Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Immunocompromised children less than 24 months of age
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is less than 24 months of age

AND

1.2 The patient is immunocompromised (e.g. receiving cancer chemotherapy, undergoing hematopoietic stem cell transplantation, or solid organ transplantation)

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th

	e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthl y doses may be needed.

Product Name: Synagis*	
Diagnosis	Cystic fibrosis (CF)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following for patients age 0 to less than 12 months:

1.1.1 Patient has cystic fibrosis

AND

1.1.2 Patient has clinical evidence of at least ONE of the following:

- Chronic lung disease (CLD)
- Nutritional compromise
- Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart

OR

1.2 BOTH of the following:

1.2.1 Patient is greater than or equal to 12 months to less than 24 months of age

AND

1.2.2 Patient has manifestations of severe lung disease including ONE of the following:

- Previous hospitalization for pulmonary exacerbation in the first year of life
- Abnormalities on chest radiography or chest computed tomography that persists when stable

- Weight for length less than the 10th percentile on a pediatric growth chart

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at:

	• Centers for Disease and Prevention (CDC) surveillance reports (http ://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prop hylaxis may receive the first dose 48 to 72 hours before discharge to h ome or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in th e hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV "season," fewer than 5 monthl y doses may be needed.

2 . Background

Benefit/Coverage/Program Information

Additional Information

In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration. [10]

- Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida.
- On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.
- Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV "season" offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10%. Use of specimens

to determine the start of the RSV “season” requires that the number of specimens tested be statistically significant.

3 . Revision History

Date	Notes
11/21/2022	Added note to guideline, PA not required for children under 2 yo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99534
Guideline Name	Systane, Refresh, Gonak, Genteal, Tears Naturale
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: brand Systane, brand Refresh, brand Gonak, brand Genteal, Tears Naturale	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- Generic equivalents for drops, ointments and gel formulations for Systane, Refresh, Gonak, Genteal, Tears Naturale, and Generic equivalent to the requested brand product
- sodium chloride ophthalmic ointment

2 . Revision History

Date	Notes
5/20/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-101395
Guideline Name	Talicia and Mycobutin
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/4/2022

1 . Criteria

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Mycobacterium Avium Complex Prophylaxis

AND

2 - Prescribed by or in consultation with an HIV or infectious disease specialist

AND

3 - Member has failed azithromycin or clarithromycin or is intolerant to the medication due to significant adverse effects or both are contraindicated

AND

4 - If request is for brand Mycobutin and the member is allergic to the generic formulation, the prescriber must submit the FDA MedWatch form

AND

5 - The requested dosage does not exceed 450 mg per day

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is responding positively to therapy

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - For doses that exceed 450mg, the use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- • United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Product Name: Mycobutin	
Diagnosis	Helicobacter pylori Infection (off-label)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of H. pylori infection

AND

2 - Prescribed in combination with amoxicillin and a proton pump inhibitor

AND

3 - If request is for brand Mycobutin, inability to use generic rifabutin (e.g., contraindications to excipients in rifabutin)

Product Name: Talicia	
Diagnosis	Helicobacter pylori Infection
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of H. pylori infection

AND

2 - The medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist

AND

3 - One of the following:

3.1 Member has tried 3 first-line treatment regimens listed in the table in background section (One of which must be Rifabutin triple therapy)

OR

3.2 Both of the following:

3.2.1 Culture and sensitivity report indicate resistance or lack of susceptibility of H. pylori to all first-line treatment regimens except Rifabutin triple therapy

AND

3.2.2 Member must have tried and failed Rifabutin triple therapy

Product Name: Mycobutin	
Diagnosis	Tuberculosis (off-label)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberculosis infection

AND

2 - Prescribed by or in consultation with an HIV or infectious disease specialist

AND

3 - Current treatment with protease inhibitors or non-nucleoside reverse transcriptase inhibitors (NNRTIs) for the treatment of HIV infection

AND

4 - If the request is for brand Mycobutin, inability to use generic rifabutin (e.g., contraindications to excipients in rifabutin).

Product Name: Mycobutin	
Diagnosis	Tuberculosis (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is responding positively to therapy

2 . Background

Benefit/Coverage/Program Information

Dosing Table

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Azithromycin	**MAC:** 1,200 mg PO once weekly or 600 mg PO twice weekly	500 mg/day
Clarithromycin	**MAC:** 500 mg PO BID	1.5 g/day
clarithromycin triple regimen	***H. pylori* infection:** 14 days: PPI (standard or double dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg or metronidazole 500 mg TID (if penicillin allergy)	See dosing regimen
bismuth quadruple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; bismuth subcitrate (120-300 mg) or subsalicylate (300 mg) QID; tetracycline 500 mg QID; metronidazole 250 mg QID or 500 mg TID-QID	See dosing regimen
concomitant regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg; Metronidazole or tinidazole 500 mg	See dosing regimen
sequential regimen	***H. pylori* infection:** 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, clarithromycin 500 mg + metronidazole/tinidazole	See dosing regimen
hybrid regimen	***H. pylori* infection:**	See dosing regimen

	7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 7 days of BID PPI, amoxicillin + clarithromycin 500 mg + metronidazole/tinidazole	
levofloxacin triple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; levofloxacin 500 mg QD; amoxicillin 1,000 mg BID	See dosing regimen
levofloxacin sequential regimen	***H. pylori* infection:**	See dosing regimen
	5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, amoxicillin + metronidazole/tinidazole + QD levofloxacin 500 mg	
rifabutin triple	***H. pylori* infection:** 10 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID + rifabutin 300 mg QD	See dosing regimen

3 . Revision History

Date	Notes
1/4/2022	Corrected Talicia criteria

Prior Authorization Guideline

Guideline ID	GL-99799
Guideline Name	Taltz - Arizona
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 BOTH of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following nonpreferred biologic products (document drug, date, and duration of trial): *

- Cimzia

AND

1.1.6 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukin umab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active psoriatic arthritis

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to THREE of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.4 History of failure, contraindication, or intolerance to THREE of the following non-preferred biologic products (document drug, date, and duration of trial):*

- Orencia
- Cimzia

- Simponi

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist

- Dermatologist

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active ankylosing spondylitis

AND

1.1.2 History of failure to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 History of failure, contraindication, or intolerance to BOTH of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.4 History of failure, contraindication, or intolerance to BOTH of the following non-preferred biologic products (document drug, date, and duration of trial):*

- Cimzia
- Simponi

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with a rheumatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active ankylosing spondylitis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Taltz	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.1.2 History of failure, contraindication, or intolerance to BOTH of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.3 History of failure, contraindication, or intolerance to BOTH of the following nonpreferred biologic products (document drug, date, and duration of trial):*

- Cimzia
- Simponi

AND

1.1.4 History of failure to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.1.6 Prescribed by or in consultation with a rheumatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz

Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
6/25/2021	Updated Program

Prior Authorization Guideline

Guideline ID	GL-99779
Guideline Name	Tarceva
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic cancer

AND

2 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

3 - Used in combination with Gemzar (gemcitabine)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent

AND

3 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR)exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g. in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of kidney cancer
- Disease is stage IV or relapsed

AND

2 - Disease is of non-clear cell histology

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from Non-Small Cell Lung Cancer (NSCLC)

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vulvar cancer

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tarceva will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tarceva therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99771
Guideline Name	Targretin
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - History of failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g. Interferons])

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has not had disease progression while on therapy

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Targretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Targretin therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-113527
Guideline Name	Tarpeyo (budesonide)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/8/2022

1 . Criteria

Product Name: Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine

ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2

AND

5 - One of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following:

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

2 . Revision History

Date	Notes
9/8/2022	Removed references, no clinical criteria changes.

Prior Authorization Guideline

Guideline ID	GL-99772
Guideline Name	Tasigna
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tasigna	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myeloid leukemia

AND

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib (Gleevec) as attested by physician

OR

2.2 Patient is currently on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive gastrointestinal stromal tumor (GIST)

AND

2 - History of failure, contraindication, or intolerance to ALL of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Tasigna	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name: Tasigna	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia and ABL1 (gene) rearrangement

AND

2 - Neoplasm is in blast or chronic phase

Product Name: Tasigna	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tasigna will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tasigna therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99652
Guideline Name	Tegsedi
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

- Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has not had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name: Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Tegsedi

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient continues to have a neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

5 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-127089
Guideline Name	Tepezza (teprotumumab-trbw)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Tepezza	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting diagnosis of thyroid eye disease (TED)

AND

2 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Specialist with expertise in the treatment of TED
- Ophthalmologist

AND

3 - Treatment with Tepezza has not exceeded a total of 8 infusions

2 . Revision History

Date	Notes
6/26/2023	Removed criteria for TED severity due to expanded indication, added ophthalmologist as prescriber option.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120594
Guideline Name	Test Strips
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Non-preferred Test Strip Products	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, contraindication, or intolerance to BOTH of the following*:

- True Metrix
- Accu-Chek

OR

2 - Patient is on an insulin pump

OR

3 - Patient is visually impaired

Notes	*See background section for plan specific preferred agents

Product Name: Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 For Insulin Dependent or Pregnant patients, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)

OR

1.2 For Non-Insulin Dependent Patients, ONE the following:

1.2.1 The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR

1.2.2 The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time

OR

1.2.3 The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time

OR

1.2.4 The patient requires additional testing due to fluctuations in blood glucose due to physical activity or exercise

OR

1.2.5 Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by OptumRx reviewing pharmacist and/or medical director)

2 . Background

Benefit/Coverage/Program Information

Preferred Test Strips According to Plan

PLAN	PREFERRED TEST STRIPS
Arizona Complete Health	OneTouch Ultra test strips OneTouch Verio test strips
Care1st	OneTouch Ultra test strips OneTouch Verio test strips
MercyCare	OneTouch meters and strips (all OneTouch products)
Banner University Family Care	Freestyle OneTouch Ultra test strips

	OneTouch Verio test strips
Health Choice	Accu-Check products
Molina	True Metrix
UHC/C&S AZ	OneTouch Ultra test strips OneTouch Verio test strips

3 . Revision History

Date	Notes
1/27/2023	Updated background chart, no changes to criteria

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144653
Guideline Name	Testosterone - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Brand Androgel pump, generic testosterone 1.62% pump (generic Androgel pump), Brand Androgel gel, generic testosterone gel (generic Androgel), testosterone enanthate, Androderm, testosterone topical 30mg/act solution, testosterone cypionate, Brand Testim, generic testosterone 50mg/5gm TD gel (generic Testim), Brand Vogelxo, generic testosterone TD gel (generic Vogelxo), Jatenzo, Kyzatrex, Tlando	
Diagnosis	Hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:	

1.1 TWO pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab, taken at separate times (Document lab value and date for both levels)

OR

1.2 BOTH of the following:

1.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.2.2 ONE pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (less than 5 ng/dL or less than 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

OR

1.3 Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

AND

2 - Patient is NOT taking ONE of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

3 - Patient is NOT taking with an Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

4 - Patient was male at birth

AND

5 - Diagnosis of hypogonadism

AND

6 - ONE of the following:

- Significant reduction in weight (less than 90 percent ideal body weight) (e.g., AIDS wasting syndrome)
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

AND

7 - If the request is for JATENZO, KYZATREX, or TLANDO, patient must have tried and failed one of the following: (Applies to Jatenzo, Kyzatrex, and Tlando only) (verified via paid pharmacy claims or submission of medical records)

- Brand Androderm or generic testosterone gel 1.62% pump
- Brand Vogelxo gel 1% (50 mg)

Product Name: Brand Androgel pump, generic testosterone 1.62% pump (generic Androgel pump), Brand Androgel gel, generic testosterone gel (generic Androgel), testosterone enanthate, Androderm, testosterone topical 30mg/act solution, testosterone cypionate, Brand Testim, generic testosterone 50mg/5gm TD gel (generic Testim), Brand Vogelxo, generic testosterone TD gel (generic Vogelxo), Jatenzo, Kyzatrex, Tlando	
Diagnosis	Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is using hormones to change physical characteristics

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

AND

3 - Patient is NOT taking ONE of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

4 - Patient is NOT taking with an Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

5 - If the request is for JATENZO, KYZATREX, or TLANDO, patient must have tried and failed one of the following: (Applies to Jatenzo, Kyzatrex, and Tlando only) (verified via paid pharmacy claims or submission of medical records)

- Brand Androderm or generic testosterone gel 1.62% pump
- Brand Vogelxo gel 1% (50 mg)

Product Name: Brand Androgel pump, generic testosterone 1.62% pump (generic Androgel pump), Brand Androgel gel, generic testosterone gel (generic Androgel), testosterone enanthate, Androderm, testosterone topical 30mg/act solution, testosterone cypionate, Brand Testim, generic testosterone 50mg/5gm TD gel (generic Testim), Brand Vogelxo, generic testosterone TD gel (generic Vogelxo), Jatenzo, Kyzatrex, Tlando	
Diagnosis	Hypogonadism, Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

OR

1.2 Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

OR

1.3 BOTH of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 ONE of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

AND

2 - Patient is NOT taking ONE of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

3 - Patient is NOT taking with an Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

2 . Revision History

Date	Notes
3/27/2024	Removed embedded step through Brand Androgel Pump. Updated st ep to include preferred agents Androderm, generic testosterone gel p ump, Brand Vogelxo gel.

Prior Authorization Guideline

Guideline ID	GL-121766
Guideline Name	Tezspire (tezepelumab-ekko)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Tezspire	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of severe asthma

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following: [2,3]

- Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months
- Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [2,3]

- High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]) [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Tezspire	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by one of the following:

- A reduction in asthma exacerbations
- Improvement in forced expiratory volume in 1 second (FEV1) from baseline

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications [4]

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

2 . Endnotes

A. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, after initiation of treatment, patients should be re-evaluated in 3 to 6 months. [4]
B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention guideline recommend patients with severe asthma should be treated with maximal optimized high dose ICS-LABA therapy. [4]

3 . Revision History

Date	Notes
2/27/2023	Added new GPI

Prior Authorization Guideline

Guideline ID	GL-99780
Guideline Name	Thalomid
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

Product Name: Thalomid	
Diagnosis	Multiple Myeloma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

AND

2 - ONE of the following:

2.1 Used for acute treatment

OR

2.2 Used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Aphthous Stomatitis or Ulcer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, recurrent aphthous stomatitis or ulcer

Product Name: Thalomid	
Diagnosis	Aphthous Stomatitis or Ulcer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Pyoderma Gangrenosum
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pyoderma gangrenosum

AND

2 - Used as third line treatment

Product Name: Thalomid	
Diagnosis	Pyoderma Gangrenosum
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous manifestations of systemic lupus erythematosus (SLE)

Product Name: Thalomid	
Diagnosis	Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Castleman's Disease (CD)

AND

2 - NOT used as first line therapy

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary myelofibrosis

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Serum erythropoietin levels less than 500 mU/mL

AND

2.1.2 History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that member has evidence of symptom improvement or reduction in spleen-liver volume while on Thalomid

Product Name: Thalomid	
Diagnosis	Acquired Immunodeficiency Syndrome (AIDS)- Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Acquired Immunodeficiency Syndrome (AIDS)- Related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - Not used as first line therapy

Product Name: Thalomid	
Diagnosis	AIDS- Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Thalomid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

2 . Revision History

Date	Notes
6/3/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-120571
Guideline Name	Thrombopoiesis Stimulating Agents
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD) • Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Preferred Drugs: Nplate, Promacta tablet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic immune thrombocytopenia (ITP)	

AND

2 - History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

Notes	*Note: Drugs may require PA

Product Name: Non-Preferred Drugs: Doptelet, Promacta powder pack/oral suspension, Tavalisse	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

2.1.2 History of failure, contraindication, or intolerance to BOTH of the following preferred alternatives*:

- Promacta Tablet (eltrombopag)*
- Nplate (romiplostim)*

OR

2.2 Patient is currently stable on requested non-preferred medication

Notes	*Note: Drugs may require PA

Product Name: Doptelet, Nplate, Promacta tablets, Promacta powder pack/oral suspension, Tavalisse	
Diagnosis	Chronic Immune (idiopathic) thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Promacta tablets, Promacta powder pack/oral suspension	
Diagnosis	Severe Aplastic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - One of the following:

2.1 Used in combination with standard immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

OR

2.2 History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

AND

3 - For Promacta powder pack/oral suspension ONLY: clinical rationale for use instead of preferred Promacta tablet

Product Name: Promacta tablets, Promacta powder pack/oral suspension	
Diagnosis	Severe Aplastic Anemia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Promacta tablet	
Diagnosis	Chronic Hepatitis C-associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic Hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

- Planning to initiate and maintain interferon-based treatment
- Currently receiving interferon-based treatment

Product Name: Promacta tablet	
Diagnosis	Chronic Hepatitis C-associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is currently on antiviral interferon therapy for treatment of chronic Hepatitis C

Product Name: Doptelet, Mulpleta	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thrombocytopenia

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - History of failure, contraindication, or intolerance to BOTH of the following preferred alternatives*:

- Promacta Tablets (eltrombopag)*
- Nplate (romiplostim)*

Notes	*Note: Drugs may require PA

Product Name: Nplate	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]

AND

2 - Patient is receiving myelosuppressive doses of radiation

2 . Revision History

Date	Notes
1/27/2023	New program, combines criteria for all drugs in class.

Prior Authorization Guideline

Guideline ID	GL-99653
Guideline Name	Tobramycin Inhalation - ARIZONA
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Bethkis, Kitabis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

Product Name: Brand TOBI Nebulizer Solution, generic tobramycin solution for inhalation, TOBI Podhaler	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Lung infection with positive culture demonstrating Pseudomonas aeruginosa infection

AND

3 - History of failure, intolerance, or contraindication to BOTH of the following

- Brand Bethkis
- Kitabis

Product Name: Brand TOBI Nebulizer Solution, generic tobramycin solution for inhalation, TOBI Podhaler	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

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Prior Authorization Guideline

Guideline ID	GL-136966
Guideline Name	Topical Capsaicin Products
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Diclareal	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of osteoarthritis of the knees

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting history of failure to ALL of the following:

- diclofenac 1% topical gel
- diclofenac 2% topical solution
- topical capsaicin cream/patch

Product Name: Trubrexa	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming requested medication is being used for the treatment of acute and chronic pain in muscles and joints associated with muscle soreness, strains, sprains, arthritis, simple backache, muscle stiffness, etc

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial and failure, contraindication, or intolerance to ALL of the following:

- diclofenac 1% topical gel
- topical capsaicin cream/patch
- topical lidocaine patch

2 . Revision History

Date	Notes
12/1/2023	New program

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Prior Authorization Guideline

Guideline ID	GL-99574
Guideline Name	Topical NSAIDs
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Flector Patch, generic diclofenac epolamine 1.3% patch	
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute pain due to minor strains, sprains, or contusions

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)
- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI (gastrointestinal) bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Product Name: Pennsaid 2%, diclofenac sodium soln 1.5%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of pain due to osteoarthritis of the knee(s)

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)
- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis

- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

AND

3 - Patient has a history of failure, intolerance, or contraindication to diclofenac topical gel 1% (Rx formulation), or Voltaren OTC (over the counter)

Product Name: generic diclofenac topical gel 1% (Rx formulation), Voltaren OTC	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of pain due to osteoarthritis of joints amenable to topical treatment, including but not limited to the hands, knees, ankles, elbows, feet, and wrists

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)

- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Prior Authorization Guideline

Guideline ID	GL-120604
Guideline Name	Trelegy Ellipta - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name: Trelegy Ellipta	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Brand Symbicort

Product Name: Trelegy Ellipta	
Diagnosis	COPD
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

AND

2 - History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of both of the following used in combination:

- Stiolto Respimat (tiotropium-olodaterol)
- Flovent HFA (fluticasone propionate)

Product Name: Trelegy Ellipta	
Diagnosis	Asthma, COPD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
1/27/2023	Added criteria for asthma indication, added reauth criteria for both C OPD and asthma.

Prior Authorization Guideline

Guideline ID	GL-99730
Guideline Name	Tremfya - AZ
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 BOTH of the following:

1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.5 Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.6 Prescribed by or in consultation with a dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

AND

2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

2.3 Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

AND

1.3 History of failure, contraindication, or intolerance to THREE of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.5 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99513
Guideline Name	Tretinoin Capsules - ARIZONA
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Tretinoin capsules	
Diagnosis	Acute Promyelocytic Leukemia (APL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute promyelocytic leukemia

Product Name: Tretinoin capsules	
Diagnosis	Acute Promyelocytic Leukemia (APL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tretinoin capsules

Product Name: Tretinoin capsules	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tretinoin capsules will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tretinoin capsules	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tretinoin capsules

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

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Prior Authorization Guideline

Guideline ID	GL-99591
Guideline Name	Tretinoin Topical
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Retin-A cream and gel*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 26 years of age or less

OR

1.2 Both of the following:

- Patient is greater than 26 years of age
- Diagnosis of acne vulgaris

AND

2 - The patient must have a history of therapeutic failure, contraindication, or intolerance to ALL of the following:

- benzoyl peroxide
- topical clindamycin
- topical erythromycin

Notes	*Only Brand Covered

2 . Revision History

Date	Notes
10/29/2021	Changed effective date to 12/1/21

Prior Authorization Guideline

Guideline ID	GL-125904
Guideline Name	Trikafta (elexacaftor/tezacaftor/ivacaftor)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name: Trikafta (80-40-60 mg) granules packet, Trikafta (100-50-75 mg) granules packet	
Diagnosis	Cystic Fibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Submission of laboratory results documenting that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data

AND

3 - Patient is between 2 and 6 years of age

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Trikafta (50-25-37.5 mg) tablet pack, Trikafta (100-50-75 mg) tablet pack	
Diagnosis	Cystic Fibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results documenting that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data

AND

3 - The patient is 6 years of age or older

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Trikafta granules packets, Trikafta tablet packs	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Trikafta therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Revision History

Date	Notes
5/19/2023	Added criteria for ages 2-6, with new corresponding granules packet s.

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Prior Authorization Guideline

Guideline ID	GL-145007
Guideline Name	Triptans - AZM
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Brand Amerge, Brand Imitrex tablets, Brand Imitrex injection, generic sumatriptan 6mg PFS, generic almotriptan, brand Maxalt, brand Maxalt MLT, Onzetra Xsail, brand Relpax, generic eletriptan, brand Treximet, generic sumatriptan naproxen, Zembrace, brand Zomig, brand Zomig ZMT, brand Frova, generic frovatriptan, Tosymra	
Diagnosis	Non-preferred products
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of migraine headaches with or without aura	

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products (document drugs, duration, and date of trials)*

- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt)
- sumatriptan (Generic Imitrex)
- zolmitriptan (Generic Zomig)

Product Name: Brand Imitrex (inj, cartridge, auto-injector and PFS), generic sumatriptan (inj, cartridge, auto-injector and PFS)*	
Diagnosis	Migraine Headaches with or without Aura
Approval Length	12 month(s)
Guideline Type	Quantity Limits

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient is currently receiving prophylactic therapy with at least ONE of the following:

3.1 Amitriptyline (Elavil)

OR

3.2 One of the following beta-blockers:

- atenolol
- metoprolol
- nadolol**
- propranolol
- timolol**

OR

3.3 Divalproex sodium (Depakote/Depakote ER)

OR

3.4 OnabotulinumtoxinA (Botox) ***

OR

3.5 Topiramate (Topamax)

OR

3.6 Venlafaxine (Effexor/Effexor XR)

OR

3.7 Calcitonin gene-related peptide (CGRP) receptor antagonists [e.g., Aimovig (erenumab), Emgality (galcanezumab)]

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See "Quantity Limits" table in background section for quantity limits ** Nadolol and timolol are non-preferred and should not be included in denial to provider *** OnabotulinumtoxinA (Botox) is a medical benefit, should not be inc luded in denial to provider

Product Name: Brand Imitrex (inj, cartridge, auto-injector and PFS), generic sumatriptan (inj, cartridge, auto-injector and PFS)*	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of cluster headaches

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See “Quantity Limits” table in background section for quantity limits

Product Name: Brand Amerge, generic naratriptan, Brand Frova, generic frovatriptan, Brand Imitrex tablets and nasal spray, generic sumatriptan tablets and nasal spray, generic almotriptan, Brand Maxalt and Maxalt MLT, generic rizatriptan and rizatriptan MLT, Onzetra Xsail, Brand Relpax, generic eletriptan, Brand Treximet, generic sumatriptan-naproxen, Zembrace Sym Touch, Brand Zomig and Zomig ZMT, generic zolmitriptan and zolmitriptan ZMT, brand Zomig nasal, generic zolmitriptan nasal spray, Tosymra *	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient is currently receiving prophylactic therapy with at least ONE of the following:

3.1 Amitriptyline (Elavil)

OR

3.2 One of the following beta-blockers:

- atenolol
- metoprolol
- nadolol**
- propranolol
- timolol**

OR

3.3 Divalproex sodium (Depakote/Depakote ER)

OR

3.4 OnabotulinumtoxinA (Botox) ***

OR

3.5 Topiramate (Topamax)

OR

3.6 Venlafaxine (Effexor/Effexor XR)

OR

3.7 Calcitonin gene-related peptide (CGRP) receptor antagonists [e.g., Aimovig (erenumab), Emgality (galcanezumab)]

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA (Food and Drug Administration) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See “Quantity Limits” table in background section for quantity limits ** Nadolol and timolol are non-preferred and should not be included in denial to provider *** OnabotulinumtoxinA (Botox) is a medical benefit, should not be inc luded in denial to provider

Product Name: Brand Zomig nasal spray, generic zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has a history of failure, contraindication, or intolerance to a trial of Imitrex Nasal Spray

AND

2 - If the request is for generic zolmitriptan nasal spray, patient must have tried and failed Brand Zomig Spray

2 . Background

Benefit/Coverage/Program Information

Quantity Limits

Quantity Limits

Drug Name	Strength	Quantity Limit
Brand Amerge generic naratriptan	1mg, 2.5mg	9 tabs/month
Brand Frova Generic frovatriptan	2.5mg	9 tabs/month
Brand Imitrex tablets generic sumatriptan tablets	25mg, 50mg, 100mg	9 tabs/month
Brand Maxalt Generic rizatriptan	5mg, 10mg	9 tabs/month
Brand Maxalt MLT Generic rizatriptan ODT	5mg, 10mg	9 tabs/month
Generic almotriptan	6.25mg, 12.5mg	6 tabs/month
Relpax Generic eletriptan	20mg, 40mg	6 tabs/month
Brand Zomig Generic zolmitriptan	2.5mg, 5mg	6 tabs/month

Brand Zomig ZMT Generic zolmitriptan ODT	2.5mg, 5mg	6 tabs/month
Brand Imitrex Nasal Spray Generic sumatriptan nasal spray	5mg, 20mg	6 spray devices/month
Zomig Nasal Spray	2.5mg, 5mg	6 spray devices/month
Treximet Generic sumatriptan/naproxen	85mg/500 mg, 10mg/60mg	9 tabs/month
Onzetra Xsail	11mg	1 box (8 units)/month
Zembrace SymTouch	3mg	1 box (4 units)/month
Brand Imitrex Generic Sumatriptan Autoinjector/Cartridge Refills	4mg/0.5mL 6mg/0.5mL	8 autoinjectors or cartridge refills/month (4 boxes/month)
Brand Imitrex Generic Sumatriptan Vials	6mg/0.5mL	10 vials/month (2 boxes/month)
Generic Sumatriptan Pre-filled Syringe	6mg/0.5mL	8 prefilled syringes (4 boxes/month)
Tosymra nasal spray	10mg	6 units per month

3 . Revision History

Date	Notes
3/28/2024	Updated guideline name. Generic sumatriptan nasal spray now prefe rred. Removed Brand Imitrex as prerequisite.

Prior Authorization Guideline

Guideline ID	GL-107465
Guideline Name	Twyneo (tretinoin-benzoyl peroxide 0.1-3% cream)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Twyneo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Both of the following:

- Patient is 9 years of age or older
- Diagnosis of acne vulgaris

AND

1.2 The patient must have a history of therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- benzoyl peroxide
- topical clindamycin
- topical erythromycin
- topical tretinoin (Brand Retin-A)

2 . Revision History

Date	Notes
5/24/2022	New program

Prior Authorization Guideline

Guideline ID	GL-99775
Guideline Name	Tykerb
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of recurrent or stage IV hormone receptor positive, human epidermal growth factor receptor 2-positive (HER2+) breast cancer

AND

1.1.2 Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of advanced or stage IV human epidermal growth factor receptor 2-positive (HER2+) breast cancer

AND

1.2.2 Used in combination with ONE of the following:

- Herceptin (trastuzumab)
- Xeloda (capecitabine)

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions

AND

1.1.2 Tykerb is active against primary (breast) tumor

AND

1.1.3 Used in combination with Xeloda (capecitabine)

OR

1.2 ALL of the following:

1.2.1 Diagnosis of recurrent intracranial or spinal ependymoma (excluding subependymoma)

AND

1.2.2 Patient has received previous radiation therapy

AND

1.2.3 Patient has received ONE of the following:

- Gross total or subtotal resection
- Localized recurrence
- Evidence of metastasis (brain, spine, or cerebral spinal fluid)

AND

1.2.4 Used in combination with Temodar (temozolomide)

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Chordoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epidermal growth factor receptor (EGFR) -positive, recurrent chordoma

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced or metastatic colon cancer (Human epidermal growth factor receptor 2 (HER2)-amplified and RAS wild type)

AND

2 - Patient has not previously been treated with a Human epidermal growth factor receptor 2 (HER2) inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

AND

3 - Patient has previously been treated with ONE of the following regimens:

- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

AND

4 - Used in combination with trastuzumab

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced or metastatic rectal cancer (Human epidermal growth factor receptor 2 (HER2)-amplified and RAS wild type)

AND

2 - Patient has not previously been treated with a Human epidermal growth factor receptor 2 (HER2) inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

AND

3 - Patient has previously been treated with ONE of the following regimens:

- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

AND

4 - Used in combination with trastuzumab

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer, Central Nervous System (CNS) Cancers, Chordoma, Colon Cancer, Rectal Cancer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tykerb will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tykerb therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-142070
Guideline Name	Tysabri (natalizumab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

Product Name: Tysabri	
Diagnosis	Crohn's Disease
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Crohn's disease has evidence of inflammation (e.g., elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes)

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting BOTH of the following*:

4.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies (document drug, date, and duration of trial):

- 6-mercaptopurine
- azathioprine
- Corticosteroids (e.g., prednisone)
- methotrexate

AND

4.2 History of failure, contraindication, or intolerance to ALL of the following** (document drug, date, and duration of trial):

- Cimzia (certolizumab pegol)
- Humira (adalimumab)
- infliximab

Notes	Note: In CD, discontinue Tysabri in patients that have not experienced therapeutic benefit by 12 weeks of induction therapy, and in patients that cannot discontinue chronic concomitant steroids within six months of starting therapy. *PA may be required **Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Tysabri	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
2/28/2024	New program, Tysabri moved from MS Agents to drug specific PA.

Prior Authorization Guideline

Guideline ID	GL-99501
Guideline Name	Uloric
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Uloric, generic febuxostat	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication or intolerance to allopurinol (generic Zyloprim)	

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-114466
Guideline Name	Ultomiris (ravulizumab-cwvz)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two preferred immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one preferred immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/26/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-128919
Guideline Name	Urea Cycle Disorder Agents
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Brand Buphenyl, generic sodium phenylbutyrate, Pheburane	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

- carbamylphosphate synthetase (CPS)
- ornithine transcarbamylase (OTC)
- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Trial and failure, or intolerance to generic sodium phenylbutyrate (applies to Brand Buphenyl and Pheburane only)

AND

4 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Olpruva, Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of urea cycle disorder (UCD)

AND

1.2 One of the following deficiencies:

- carbamylphosphate synthetase (CPS)
- ornithine transcarbamylase (OTC)
- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Inadequate response to one of the following:

- Dietary protein restriction
- Amino acid supplementation

AND

4 - Trial and failure, contraindication, or intolerance to generic sodium phenylbutyrate

AND

5 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

6 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Brand Buphenyl, generic sodium phenylbutyrate, Olpruva, Pheburane, Ravicti

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., plasma ammonia and amino acid levels within normal limits)

AND

2 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

2 . Revision History

Date	Notes
7/28/2023	Added Olpruva as NP target

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99693
Guideline Name	Valchlor
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Chronic or smoldering T-cell leukemia-lymphoma
- Primary cutaneous marginal zone or follicle center B-cell lymphoma
- Lymphomatoid papulosis (LyP) with extensive lesions
- Mycosis fungoides (MF)-Sezary syndrome (SS)

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Valchlor will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Valchlor therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-114467
Guideline Name	Valsartan oral solution
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Valsartan oral solution	
Diagnosis	Patients 7 years of age or older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 7 years of age or older

AND

2 - Patient cannot take solid dosage form due to swallowing issues

2 . Revision History

Date	Notes
9/26/2022	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99527
Guideline Name	Vancomycin - AZ
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	10 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]

AND

2 - If the request is for vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq and vancomycin capsules*

Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	12 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of Clostridioides difficile infection [previously known as Clostridium difficile-associated diarrhea] after prior treatment with oral vancomycin

Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Staphylococcus aureus
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Enterocolitis due to Staphylococcus aureus

AND **2** - If the request is for vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq and vancomycin capsules*	
Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99655
Guideline Name	Vecamyl
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately severe to severe essential hypertension

OR

2 - Diagnosis of uncomplicated malignant hypertension

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Vecamyl therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-116195
Guideline Name	Velphoro (sucroferric oxyhydroxide), Auryxia (ferric citrate)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Velphoro, Auryxia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following

- Diagnosis of hyperphosphatemia
- Diagnosis of End Stage Renal Disease

AND

2 - Adherence to and trial and failure to one of the following at maximum dosages (MUST be verified via paid pharmacy claims or submission of medical records) • Sevelamer Carbonate at the maximum dosage – 800mg/15 per day • Sevelamer Powder Packets at maximum dosage – 2.4gm packet 4 per day	
Notes	1. Approval will not be granted for requests based on potential side effects, i.e., constipation 2. Approval will not be granted for submitted prior authorizations based on pill burden. Velphoro and Sevelamer are both taken 3 times a day.

2 . Revision History

Date	Notes
10/28/2022	Removed Fosrenol as prerequisite option

Prior Authorization Guideline

Guideline ID	GL-139341
Guideline Name	Velsipity (etrasimod)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Velsipity	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to ALL of the following*** (document drug, date, and duration of trial):

- Humira (adalimumab)
- infliximab
- Xeljanz oral tablet (tofacitinib)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Velsipity	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

2 . Revision History

Date	Notes
1/23/2024	New program

Prior Authorization Guideline

Guideline ID	GL-114517
Guideline Name	Veltassa
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Veltassa	
Diagnosis	Non-Life Threatening Hyperkalemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-life threatening hyperkalemia

AND

2 - Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs [NSAIDs]) have been discontinued or reduced to the lowest effective dose

AND

3 - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

4 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

AND

5 - History of failure, intolerance, or contraindication to Lokelma

Product Name: Veltassa	
Diagnosis	Non-Life Threatening Hyperkalemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a positive clinical response to Veltassa therapy

AND

2 - Patient continues to require treatment for hyperkalemia

AND

3 - Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs [NSAIDs])) have been discontinued or reduced to the lowest effective dose

2 . Revision History

Date	Notes
9/26/2022	Added step through preferred Lokelma

Prior Authorization Guideline

Guideline ID	GL-117632
Guideline Name	Vemlidy
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Vemlidy	
Diagnosis	Treatment-Naïve Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a contraindication to entecavir therapy

AND

2 - Patient is 12 years of age or older

Product Name: Vemlidy	
Diagnosis	Treatment-Experienced Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Patient is currently on Viread therapy

AND

1.1.2 ONE of the following:

- Patient has a creatinine clearance less than 60 mL per minute
- Patient has a diagnosis of osteoporosis

AND

1.1.3 Patient is 12 years of age or older

OR

1.2 Patient is currently on Vemlidy therapy

2 . Revision History

Date	Notes
12/4/2022	Added age requirement, changed from ST to PA

Prior Authorization Guideline

Guideline ID	GL-135321
Guideline Name	Veopoz (pozelimab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name: Veopoz	
Diagnosis	CD55-deficient protein-losing enteropathy (PLE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease

AND

1.2 Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation

AND

1.3 Patient is 1 year of age or older

AND

1.4 Patient has hypoalbuminemia (serum albumin concentration of ≤ 3.2 g/dL)

AND

1.5 Patient has at least one of the following signs or symptoms within the last six months:

- abdominal pain
- diarrhea
- peripheral edema
- facial edema

AND

2 - Prescribed by or in consultation with one of the following:

- Immunologist
- Geneticist
- Hematologist

Product Name: Veopoz	
Diagnosis	CD55-deficient protein-losing enteropathy (PLE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g. decrease in albumin transfusions and hospitalizations, normalization of serum IgG concentrations, etc.)	

2 . Revision History

Date	Notes
10/23/2023	New program

Prior Authorization Guideline

Guideline ID	GL-128985
Guideline Name	Veozah (fezolinetant)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Veozah	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

AND

2 - Submission of medical records (e.g., chart notes, paid claims history) documenting trial

and failure, contraindication, or intolerance to both of the following (document drug, date, and duration of trial):

- Menopausal hormone therapy (e.g., Premarin, Bijuva, Estrogel, etc.)
- Non-hormonal therapy (e.g. paroxetine mesylate, venlafaxine, clonidine, etc.)

Product Name: Veozah	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline, etc.)

2 . Revision History

Date	Notes
7/26/2023	New program

Prior Authorization Guideline

Guideline ID	GL-107454
Guideline Name	Verkazia (cyclosporine ophthalmic emulsion 0.1%)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Verkazia	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia)

AND

1.2 Trial and failure, contraindication, or intolerance to one of the following (verified via pharmacy paid claims or submission of medical records):

- Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)
- Topical ophthalmic mast cell stabilizers (e.g., cromolyn)

AND

1.3 Trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone) ((verified via pharmacy paid claims or submission of medical records)

AND

2 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

Product Name: Verkazia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia)

2 . Revision History

Date	Notes
5/24/2022	New program

Prior Authorization Guideline

Guideline ID	GL-108523
Guideline Name	Vijoice (alpelisib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Vijoice	
Approval Length	6 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - Submission of documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Submission of documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

AND

5 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

Product Name: Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation of positive clinical response to therapy (e.g., radiological response defined as a ≥ 20% reduction from baseline in the sum of target lesion volume)

AND

2 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

2 . Revision History

Date	Notes

6/22/2022	New program

Prior Authorization Guideline

Guideline ID	GL-99535
Guideline Name	Vitamin B-12
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vitamin B-12	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin B-12 deficiency.	

2 . Revision History

Date	Notes

5/20/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99532
Guideline Name	Vitamin C
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vitamin C	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin C deficiency	

2 . Revision History

Date	Notes

5/19/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99533
Guideline Name	Vitamin D
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vitamin D	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin D deficiency	

2 . Revision History

Date	Notes

5/19/2021	7/1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-114156
Guideline Name	Vivjoa (oteseconazole)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Vivjoa	
Approval Length	4 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis (RVVC)

AND

2 - Patient is NOT of reproductive potential

AND

3 - Diagnosis of RVVC confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Vaginal fungal culture

AND

4 - Patient has experienced 3 or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the past 12 months

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- One intravaginal product (e.g., clotrimazole, miconazole, tioconazole, terconazole, boric acid)
- Oral fluconazole

2 . Revision History

Date	Notes
9/26/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-107466
Guideline Name	Vonjo (pacritinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of ONE of the following:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

1.2 Disease is intermediate or high risk

AND

1.3 Pre-treatment platelet count below 50 x 10^9 L

AND

2 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Oncologist

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

Product Name: Vonjo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - This drug will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B	

2 . Revision History

Date	Notes
5/24/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-143518
Guideline Name	Vonoprazan Containing Agents
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Voquezna Dual Pak, Voquezna Triple Pak	
Diagnosis	Helicobacter pylori (H. pylori) Infection
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Helicobacter pylori infection

AND

2 - Trial and failure, contraindication, or intolerance to BOTH of the following first line treatment regimens:

- Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy) [D]
- Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

Product Name: Voquezna	
Diagnosis	Helicobacter pylori (H. pylori) Infection
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Helicobacter pylori infection

AND

2 - One of the following:

- Used in combination with amoxicillin and clarithromycin for the treatment of H. pylori infection
- Used in combination with amoxicillin for the treatment of H. pylori infection

AND

3 - Trial and failure, contraindication, or intolerance to BOTH of the following first line treatment regimens:

- Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy) [D]
- Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

Product Name: Voquezna	
Diagnosis	Healing and Relief of Heartburn associated with Erosive Esophagitis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of erosive esophagitis

AND

2 - Used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis

AND

3 - Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's):

- omeprazole
- esomeprazole
- pantoprazole
- lansoprazole
- rabeprazole
- dexlansoprazole

Product Name: Voquezna	
Diagnosis	Maintenance of Healing and Relief of Heartburn associated with Erosive Esophagitis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used to maintain healing and relief of heartburn associated with erosive esophagitis

AND

2 - Trial (of a minimum 8-week supply) and inadequate response (within the last 365 days), contraindication, or intolerance to TWO of the following generic proton pump inhibitors (PPI's):

- omeprazole
- esomeprazole
- pantoprazole
- lansoprazole
- rabeprazole
- dexlansoprazole

2 . Revision History

Date	Notes
2/29/2024	Changed guideline name. Added criteria for Voquezna.

Prior Authorization Guideline

Guideline ID	GL-99701
Guideline Name	Votrient
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

- Disease is relapsed
- Stage IV disease

Product Name: Votrient	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of ONE of the following:

- Angiosarcoma
- Alveolar soft part sarcoma
- Pleomorphic rhabdomyosarcoma
- Retroperitoneal/Intra-abdominal disease that is unresectable or progressive
- Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases
- Solitary fibrous tumor/hemangiopericytoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of progressive gastrointestinal stromal tumors (GIST)

AND

1.2.2 History of failure, contraindication, or intolerance to ALL of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)

- Stivarga (regorafenib)

Product Name: Votrient	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 ONE of the following:

- Disease is refractory to radioactive iodine treatment
- Distant metastatic disease not amenable to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Votrient	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - One of the following:

- Disease is recurrent
- Disease is metastatic

AND

3 - Disease has progressed following previous cytotoxic chemotherapy (e.g., doxorubicin, docetaxel/gemcitabine, etc.)

Product Name: Votrient	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - ONE of the following:

- Disease is persistent
- Disease is recurrent

Product Name: Votrient

Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer, Soft Tissue Sarcoma (STS), Thyroid Carcinoma, Uterine Sarcoma, Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Product Name: Votrient	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Votrient will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Votrient	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Votrient therapy

2 . Revision History

Date	Notes
4/13/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-137865
Guideline Name	Voxzogo (vosoritide)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/15/2023

1 . Criteria

Product Name: Voxzogo	
Diagnosis	Achondroplasia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has open epiphyses

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of achondroplasia as confirmed by one of the following: [2, 3]

2.1 Both of the following:

2.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

2.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

2.2 Molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

3 - Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Product Name: Voxzogo

Diagnosis	Achondroplasia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to have open epiphyses

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by one of the following:

- Improvement in annualized growth velocity (AGV) compared to baseline
- Improvement in height Z-score compared to baseline

AND

3 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Product Name: Voxzogo	
Diagnosis	Idiopathic Short Stature (ISS)
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage for diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved

Notes	Approval Length: N/A - Requests for Idiopathic Short Stature (ISS) sh ould not be approved. Deny as a benefit exclusion.

2 . Revision History

Date	Notes
12/15/2023	Updated effective date

Prior Authorization Guideline

Guideline ID	GL-112050
Guideline Name	Vtama (tapinarof)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2022

1 . Criteria

Product Name: Vtama	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting a diagnosis of plaque psoriasis

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting a minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies:

- Corticosteroids (e.g., betamethasone, clobetasol)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Vtama	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting positive clinical response to therapy as evidenced by one of the following:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

2 . Revision History

Date	Notes
8/19/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-131923
Guideline Name	Vyjuvek (beremagene geperpavec-svdt)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Vyjuvek	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of dystrophic epidermolysis bullosa (DEB)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

AND

3 - Medication is being used for the treatment of wounds

AND

4 - Patient is 6 months of age or older

AND

5 - Medication will be applied by a healthcare professional

AND

6 - Submission of medical records (e.g., chart notes) confirming wound(s) being treated meet all of the following criteria [2]:

- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection in the wound being treated
- No evidence or history of squamous cell carcinoma in the wound being treated

AND

7 - Prescribed by or in consultation with a dermatologist

Product Name: Vyjuvek	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response (e.g., decrease in wound size, increase in granulation tissue, complete wound closure)

AND

2 - Wound(s) being treated meet all of the following criteria [2]:

- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection in the wound being treated
- No evidence or history of squamous cell carcinoma in the wound being treated

2 . Revision History

Date	Notes
8/29/2023	New program

Prior Authorization Guideline

Guideline ID	GL-99867
Guideline Name	Vyndaqel and Vyndamax
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)	

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following

2.3.1 Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

AND

2.3.2 Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*

AND

2.3.3 Absence of monoclonal protein identified in serum, urine immunofixation (IFE), serum free light chain (sFLC) assay

AND

3 - Prescribed by, or in consultation, with a cardiologist

AND

4 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

AND

5 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

5.1 ONE of the following:

5.1.1 Patient has New York Heart Association (NYHA) Functional Class I or II heart failure

OR

5.1.2 BOTH of the following:

5.1.2.1 Patient has New York Heart Association (NYHA) Functional Class III heart failure

AND

5.1.2.2 Patient's cardiopulmonary functional status allows patient to ambulate 100 meters or greater in six minutes or less

AND

5.2 Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 picograms/milliliter

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) verifying patient is not receiving Vyndaqel or Vyndamax in combination with either of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

OR

6.2 If the patient is receiving Vyndaqel/Vyndamax in combination with Onpattro (patisiran) or Tegsedi (inotersen), the physician attests that he/she will coordinate care with other specialist(s) involved in the patient's amyloidosis treatment plan to determine optimal long term monotherapy** treatment regimen

Notes	NOTE: *May require prior authorization and notification ** Referring to monotherapy with Vyndaqel/Vyndamax, Onpattro, or T egsedi

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that the patient has experienced a positive clinical response to Vyndaqel or Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Prescribed by or in consultation with a cardiologist

AND

3 - Submission of medical records (e.g., chart notes) documenting that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Paid claims or submission of medical records (e.g., chart notes) verifying patient is not receiving Vyndaqel or Vyndamax in combination with either of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

2 . Revision History

Date	Notes
12/9/2021	Added submission of records/paid claims where applicable.

Prior Authorization Guideline

Guideline ID	GL-131957
Guideline Name	Vyvgart (efgartigimod alfa-fcab)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Vyvgart, Vyvgart Hytrulo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - For Vyvgart Hytrulo, trial and failure or intolerance to Vyvgart IV infusion

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Vyvgart, Vyvgart Hytrulo	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

2 . Revision History

Date	Notes
8/29/2023	Added Vyvgart Hytrulo to PA

Prior Authorization Guideline

Guideline ID	GL-144885
Guideline Name	Wainua (eplontersen)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name: Wainua	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has a transthyretin (TTR) mutation (e.g., V30M)

AND

3 - Submission of medical records (e.g., chart notes) confirming one of the following:

- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) greater than or equal to 10 and less than or equal to 130
- Patient has a baseline Karnofsky Performance Status score greater than 50%

AND

4 - Presence of clinical signs and symptoms of the disease (e.g., neuropathy, quality of life)

AND

5 - Patient has not had a liver transplant

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Wainua	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart note) documenting a positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms from baseline (e.g., neuropathy, quality of life, lower serum TTR level)

AND

2 - Submission of medical records (e.g., chart notes) confirming one of the following:

- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) greater than or equal to 10 and less than or equal to 130
- Patient continues to have a Karnofsky Performance Status score greater than 50%

AND

3 - Patient has not had a liver transplant

2 . Revision History

Date	Notes
3/26/2024	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99732
Guideline Name	Wakix
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Wakix	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to the following: Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - One of the following:

3.1 Patient has a history of failure, contraindication, or intolerance to all of the following:

3.1.1 One of the following:

- An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine)
- A methylphenidate-based stimulant

AND

3.1.2 Armodafinil (Nuvigil)

AND

3.1.3 Sunosi (solriamfetol)

OR

3.2 Patient has a history of or potential for a substance abuse disorder

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Wakix	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a reduction in symptoms of excessive daytime sleepiness associated with Wakix therapy

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-99695
Guideline Name	Xalkori
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name: Xalkori	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive
- Tumor is positive for mesenchymal-epithelial transition (MET) amplification
- Tumor is positive for MET exon 14 skipping mutation

Product Name: Xalkori	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

Product Name: Xalkori

Diagnosis	Inflammatory Myofibroblastic Tumor (IMT), Non-Small Cell Lung Cancer (NSCLC), Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xalkori therapy

Product Name: Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xalkori will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xalkori therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

Guideline ID	GL-136961
Guideline Name	Xdemvy (lotilaner)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name: Xdemvy	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Diagnosis of Demodex blepharitis

AND

1.2 Patient exhibits one of the following signs of Demodex infestation

- Collarettes
- Eyelid margin erythema
- Eyelash anomalies (e.g., eyelash misdirection)

AND

1.3 Patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward)

AND

1.4 Trial and inadequate response to tea tree-oil shampoo or eyelid scrub

AND

2 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

2 . Revision History

Date	Notes
11/27/2023	New program

Prior Authorization Guideline

Guideline ID	GL-115528
Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/18/2022

1 . Criteria

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to all of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib) immediate-release tablets
- Orencia (abatacept)

AND

1.4 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib) immediate-release
- Orencia (abatacept)

AND

1.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

1.2 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to Xeljanz (tofacitinib) immediate release tablets

AND

1.4 Prescribed by or in consultation with a gastroenterologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active UC

AND

2.3 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication, or intolerance to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3.1.2 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to all of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib) immediate-release tablets

OR

3.2 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication, or intolerance to one of the following nonbiologic DMARDs:

- leflunomide
- methotrexate

AND

3.1.2 History of failure, contraindication, or intolerance to all of the following (applies to oral solution ONLY):

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib) immediate-release tablets
- Orencia (abatacept)

OR

3.2 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
10/18/2022	Corrected dx in PJIA initial auth criteria

Prior Authorization Guideline

Guideline ID	GL-99657
Guideline Name	Xenazine
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chorea in patients with Huntington's disease	

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off Label)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia

AND

2 - One of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome

AND

2 - History of failure, contraindication, or intolerance to Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99529
Guideline Name	Xenleta
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xenleta	
Diagnosis	Community-acquired bacterial pneumonia
Approval Length	7 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 All of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

AND

1.3.3 History of failure, contraindication, or intolerance to three of the following antibiotics:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Xenleta*	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR **1.2** As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **1.3** The medication is being prescribed by or in consultation with an infectious disease specialist	
Notes	*Approval Duration: Based on provider recommended treatment durations, not to exceed 6 months

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-131958
Guideline Name	Xenpozyme (olipudase alfa)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name: Xenpozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acid sphingomyelinase deficiency (ASMD)*

AND

2 - Disease confirmed by ONE of the following: [2]

2.1 Molecular genetic testing confirms biallelic pathogenic variants in the SMPD1 (sphingomyelin phophodiesterase-1) gene

OR

2.2 Residual acid sphingomyelinase activity that is less than 10% of controls (in peripheral blood lymphocytes or cultured skin fibroblasts)

AND

3 - Submission of medical records (e.g., chart notes) documenting patient has non-central nervous system manifestations of ASMD

AND

4 - Prescribed by or in consultation with ONE of the following:

- Metabolic disease specialist
- Geneticist

Notes	*Acid Sphingomyelinase Deficiency is also known as Niemann-Pick Disease types A, A/B, and B [1]

Product Name: Xenpozyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., decrease in spleen size, decrease in liver size, increase in platelet count, improved lung function)

2 . Revision History

Date	Notes
8/29/2023	Added new GPI for 4 mg strength

Prior Authorization Guideline

Guideline ID	GL-99658
Guideline Name	Xermelo
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome diarrhea

AND

2 - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

AND

3 - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xermelo

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99659
Guideline Name	Xolair
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate or severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80 percent predicted [in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - ONE of the following:

3.1 Baseline (pre-omalizumab treatment) serum total Immunoglobulin E (IgE) level greater than or equal to 30 IU/mL (international units per milliliter) and less than or equal to 1500 IU/mL

OR

3.2 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

4 - Positive skin test or in vitro reactivity to a perennial aeroallergen

AND

5 - Used in combination with ONE of the following:

5.1 One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)-long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate-salmeterol (AirDuo, Advair), budesonide-formoterol (Symbicort)]

OR

5.2 Combination therapy including BOTH of the following:

5.2.1 One high-dose (appropriately adjusted for age) inhaled corticosteroid (ICS) product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

5.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

6 - Patient is not receiving Xolair in combination with ONE of the following:

- Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

AND

7 - Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

AND

8 - Prescribed by or in consultation with an allergist-immunologist or pulmonologist

Product Name: Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by ONE of the following:

- reduction in frequency of exacerbations
- decreased utilization of rescue medications
- increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing controller medication

AND

3 - Patient is not receiving Xolair in combination with ONE of the following:

- Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

AND

4 - Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

AND

5 - Prescribed by or in consultation with allergist-immunologist or pulmonologist

Product Name: Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic urticaria

AND

2 - ONE of the following:

2.1 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*

OR

2.2 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to BOTH of the following taken in combination:

2.2.1 Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.2.2 ONE of the following:

- Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*
- H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- Leukotriene modifier [e.g., Singulair (montelukast)]

AND

3 - Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

AND

4 - Prescribed by or in consultation with an allergist-immunologist or dermatologist

Notes	*Patients 65 years of age and older in whom first generation H1-antihi stamines are considered high risk medications to be avoided (e.g., Be ers criteria, HEDIS) should be directed to try alternatives that are not c onsidered high risk.

Product Name: Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)

AND

2 - Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by or in consultation with allergist-immunologist or dermatologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-99502
Guideline Name	Xopenex Respules
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Xopenex inhalation soln, generic levalbuterol inhalation soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - The patient has a history of failure, contraindication, or intolerance to treatment with albuterol inhalation solution	

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-139344
Guideline Name	Xphozah (tenapanor)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Xphozah	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hyperphosphatemia in chronic kidney disease

AND

2 - Patient is on dialysis

AND

3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and inadequate response (minimum 30-day supply), contraindication or intolerance to ALL of the following:

- calcium carbonate
- calcium acetate
- sevelamer carbonate

Product Name: Xphozah	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and inadequate response (minimum 30-day supply), contraindication or intolerance to ALL of the following::

- calcium carbonate
- calcium acetate
- sevelamer carbonate

2 . Revision History

Date	Notes
1/23/2024	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99660
Guideline Name	Xuriden
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of a hereditary orotic aciduria	

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xuriden therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

Guideline ID	GL-142073
Guideline Name	Zeposia (ozanimod)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least TWO of the preferred alternatives * (May require PA) (Verified via pharmacy paid claims or submission of medical records)

- Avonex
- Brand Copaxone
- generic dalfampridine
- generic dimethyl fumarate
- generic fingolimod
- Kesimpta
- Ocrevus
- Rebif
- generic teriflunomide
- Tysabri

Notes	*Note: Preferred alternatives may require PA

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting BOTH of the following*:

3.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies (document drug, date, and duration of trial):

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

3.2 History of failure, contraindication, or intolerance to ALL of the following** (document drug, date, and duration of trial):

- Humira (adalimumab)
- infliximab
- Xeljanz oral tablet (tofacitinib)

Notes	*PA may be required **Patients requesting initial authorization who were established on the rapy via the receipt of a manufacturer supplied sample at no cost in th e prescriber's office or any form of assistance from manufacturer spon sored programs shall be required to meet initial authorization criteria a s if patient were new to therapy.

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
2/28/2024	updated preferred agent prerequisites, updated MS reauth criteria (a dded examples)

Prior Authorization Guideline

Guideline ID	GL-114472
Guideline Name	Zimhi (naloxone)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Zimhi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of failure, or intolerance to preferred naloxone products (e.g., Brand Narcan nasal spray, Kloxxado, preferred naloxone injections)	

2 . Revision History

Date	Notes

9/26/2022	New program

Prior Authorization Guideline

Guideline ID	GL-133807
Guideline Name	Zinplava (bezlotoxumab)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name: Zinplava	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

1.1 Used for the reduction of the recurrence of Clostridium difficile infection (CDI)

AND

1.2 Patient is 1 year of age or older

AND

1.3 Used in combination with antibacterial drug treatment for CDI [e.g., oral Vancocin (vancomycin), Flagyl (metronidazole), or Dificid (fidaxomicin)]

AND

1.4 Patient has one or more of the following risk factors associated with CDI recurrence:

- One or more prior episodes of CDI in the previous 6 months
- Immunocompromised
- Chronic dialysis
- Inflammatory bowel disease
- Continued use of non-CDI antimicrobials after diagnosis of CDI and/or after CDI treatment

AND

2 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Gastroenterologist

2 . Revision History

Date	Notes
9/26/2023	New Program

Prior Authorization Guideline

Guideline ID	GL-124879
Guideline Name	Zolgensma (onasemnogene abeparvovec-xioi)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Zolgensma	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - The mutation or deletion of genes in chromosome 5q resulting in one of the following: [1-8, A]

1.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

1.2 Compound heterozygous mutation of SMN1 gene (e.g., deletion of Survival of Motor Neuron 1 [SMN1] exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2 - One of the following:

2.1 Both of the following: [1-5]

2.1.1 Diagnosis of diagnosis of SMA Type 0, I or Type II spinal muscular atrophy (SMA) confirmed by a neurologist with expertise in the treatment of SMA

AND

2.1.2 Patient is less than or equal to 2 years of age

OR

2.2 Both of the following:

2.2.1 Diagnosis of SMA based on the results of SMA newborn screening

AND

2.2.2 Patient has 3 copies or less of Survival of Motor Neuron 2 (SMN 2)

AND

3 - Patient is not dependent on either of the following:

- Invasive ventilation or tracheostomy
- Use of invasive ventilation beyond use of naps and nighttime sleep

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting patient's anti-AAV9 antibody titers are less than or equal to 1:50 [1]

AND

5 - Patient is not to receive concomitant SMN modifying therapy (e.g. Spinraza)

AND

6 - Prescribed by a neurologist with expertise in the diagnosis of SMA

AND

7 - Patient has never received Zolgensma treatment in their lifetime

2 . Revision History

Date	Notes
4/20/2023	Added new GPIs, no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-99503
Guideline Name	Zontivity
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zontivity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- History of myocardial infarction (MI)
- Peripheral arterial disease (PAD)

AND

2 - Patient does not have a history of ONE of the following:

- Stroke
- Transient ischemic attack (TIA)
- Intracranial hemorrhage (ICH)

AND

3 - Patient does not have active pathological bleeding

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-99504
Guideline Name	Zortress - ARIZONA
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zortress	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Kidney transplant rejection prophylaxis in patients at low-moderate immunologic risk

OR

2 - Liver transplant rejection prophylaxis

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

Guideline ID	GL-144736
Guideline Name	Zoryve (roflumilast)
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	3/22/2024

1 . Criteria

Product Name: Zoryve cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of plaque psoriasis

AND

2 - Patient is 6 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) or paid claims history documenting a minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies (trial must be from two different classes):

- Corticosteroids (e.g., betamethasone, clobetasol)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Zoryve cream	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy as evidenced by one of the following:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting a diagnosis of seborrheic dermatitis

AND

2 - Patient is 9 years of age or older

AND

3 - Submission of medical records (e.g., chart notes) or paid claims history documenting a minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies (trial must be from two different classes):

- Corticosteroids (e.g., betamethasone, clobetasol)
- Antifungals (e.g., ciclopirox, ketoconazole)
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy as evidenced by improvement from baseline for one of the following:

- Scaling
- Erythema
- Pruritis
- Body surface area (BSA) involvement

2 . Revision History

Date	Notes
3/21/2024	Updated submission of records verbiage for clarity per PA Team request. No change to clinical intent.

Prior Authorization Guideline

Guideline ID	GL-114155
Guideline Name	Ztalmy (ganaxolone)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	10/1/2022

1 . Criteria

Product Name: Ztalmy	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) confirming diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

AND

2 - Patient has a mutation in the CDKL5 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Patient is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic)

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to two preferred anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine)

OR

5.2 For continuation of prior therapy

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ztalmy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by a reduction in the frequency of seizures from baseline

2 . Revision History

Date	Notes
9/20/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-139356
Guideline Name	Zurzuvae (zuranolone)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name: Zurzuvae	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of severe postpartum depression (PPD)

OR

1.2 Both of the following:

1.2.1 Diagnosis of mild to moderate postpartum depression (PPD)

AND

1.2.2 Trial and failure, contraindication or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine)

AND

2 - Patient is 18 years of age or older

AND

3 - Onset of symptoms in the third trimester or within 4 weeks of delivery

AND

4 - Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae

2 . Revision History

Date	Notes
1/23/2024	New program

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116186
Guideline Name	Zynteglo (betibeglogene autotemcel)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name: Zynteglo	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of transfusion-dependent beta-thalassemia as confirmed by the presence of a mutation at both alleles of the β-globin gene (i.e., β0/β0, β0/β+, β+/β+, β0/βE)

AND

2 - One of the following:

- Patient has a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs)
- Patient requires 8 or more red blood cell (RBC) transfusions per year

AND

3 - Patient is 4 years of age or older [A]

AND

4 - Patient is ineligible for an allogeneic hematopoietic stem cell transplant with an HLA-identical sibling donor [B]

AND

5 - Provider attests that patient is clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT) and has not received any prior gene therapy or HSCT

AND

6 - Patient has obtained a negative test result for all of the following prior to cell collection:

- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2)
- Human immunodeficiency virus (HIV)

AND

7 - Patient is able to provide an adequate number of cells to meet the minimum recommended dose of 5 x 10^6 CD34+ cells/kg

AND

8 - Patient does not have any of the following [1-4]:

- Severely elevated iron in the heart (e.g., patients with cardiac T2* less than 10 msec by MRI)
- Advanced liver disease
- MRI results of the liver demonstrating liver iron content greater than or equal to 15 mg/g (unless biopsy confirms absence of advanced disease)

AND

9 - Both of the following:

- Iron chelation therapy (e.g., deferoxamine, deferasirox) will be discontinued for at least 7 days prior to initiating myeloablative conditioning therapy
- Prophylactic HIV anti-retroviral medications (e.g., Truvada, Descovy) or hydroxyurea will be discontinued for at least one month prior to mobilization (or for the expected duration for elimination of those medications)

AND

10 - Prescribed by a stem cell transplant specialist

AND

11 - Patient has never received Zynteglo treatment in their lifetime

2 . Endnotes

A. The safety and efficacy of Zynteglo in children less than 4 years of age have not been established. [1]
B. Per consultant feedback, Zynteglo should be reserved for patients who do not have an HLA-identical sibling for an allogeneic hematopoietic stem cell transplant. [5]

3 . Revision History

Date	Notes

10/28/2022	New Program

Prior Authorization Guideline

Guideline ID	GL-99578
Guideline Name	Zyvox
Formulary	• Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Labeled Uses
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following: **1.1** For continuation of therapy upon hospital discharge	

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 ONE of the following diagnoses:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Skin and skin structure infections (complicated and uncomplicated)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Zyvox

OR

1.4 Invasive infection caused by or likely to be caused by vancomycin-resistant Enterococcus faecium (VRE)

Notes	*Approval Duration: For vancomycin-resistant Enterococcus faecium, authorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All other approvals will be issued for 14 days.

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Off label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge **OR** **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **3** - The medication is being prescribed by or in consultation with an Infectious Disease specialist	
Notes	*Approval Duration: Based on provider recommended treatment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
7/21/2021	Update guideline