AHCCCS
Arizona Health Care Cost Containment System

AHCCCS Pharmacy and Therapeutics Committee

February 17, 2016

Introductions

Dr. Sara Salek, Chief Medical Officer

AHCCCS

Agenda

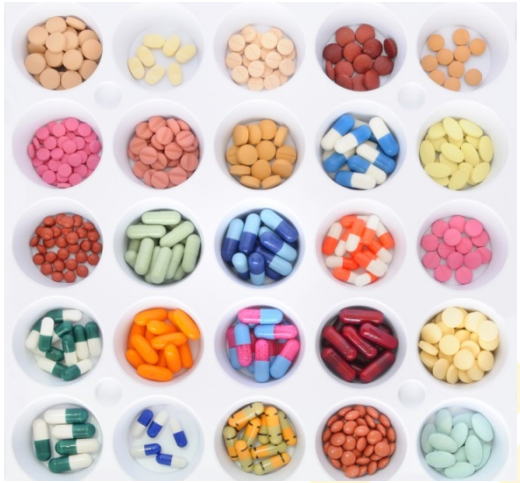
1. Overview of P&T Committee
2. Supplemental Rebate Class Review: Inhaled Glucocorticoids
3. Benzodiazepine Proposed Quantity Limits
4. Drug List Change Requests
5. New Drug Reviews: Non-supplemental rebate class
6. BH Drug List Request

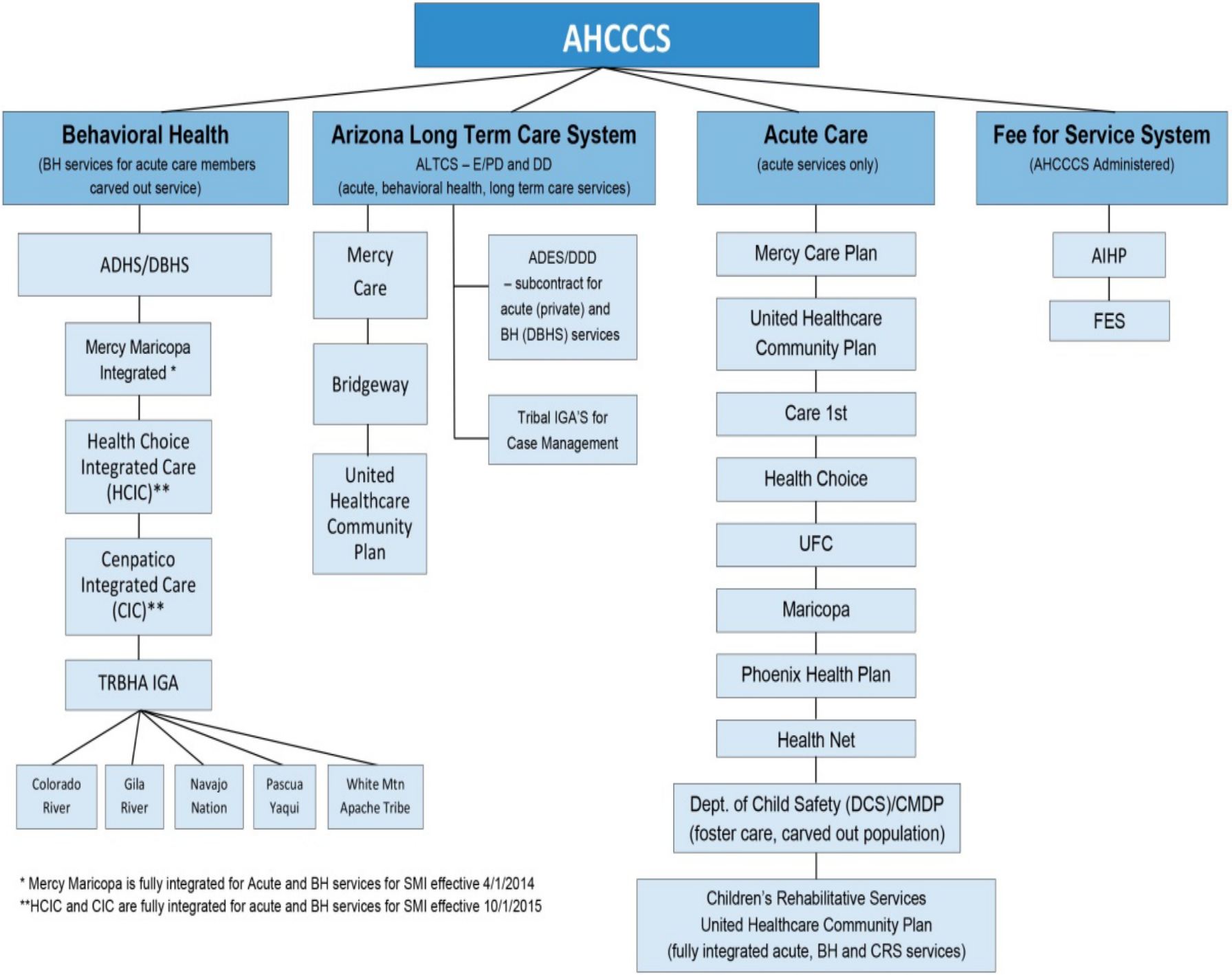
AHCCCS Overview

- 1,836,578 members as of 2/1/16
- Over 12 billion in expenditures annually
  - ~10% on Pharmacy

AHCCCS Coverage: Medications

1. Medically necessary
2. Cost effective
3. Federally reimbursable





* Mercy Maricopa is fully integrated for Acute and BH services for SMI effective 4/1/2014
**HCIC and CIC are fully integrated for acute and BH services for SMI effective 10/1/2015

Overview of P&T Committee

Dr. Salek

P&T Composition: AHCCCS Members

- AHCCCS
- Health Care Providers
- Members of Public
- MCOs

Regulations Governing P&T

- Drug Utilization Review Board (DURB)
  - Sec 1927 SS Act
  - AHCCCS waived in State Plan
  - Drug rebate program req. for MCO/FFS
- Pharmacy and Therapeutics Committee

Committee Purpose

- Evaluate scientific evidence of the relative safety, efficacy, effectiveness and clinical appropriateness of prescription drugs.
- Development and maintenance of a statewide drug list and prior authorization criteria as appropriate.
- Evaluate drugs in an unbiased manner emphasizing the best clinical evidence and cost effectiveness.

Committee Functions

- Review the AHCCCS Drug List at a minimum annually.
- Review new drugs and biosimilars 180 days from the date the drug is commercially available.
- Provide recs on the grandfathering status of each non-preferred drug for each supplemental therapeutic class reviewed by the Committee.
- Respond to requests for medication additions, deletions or changes to the AHCCCS Drug List

Committee Functions: AHCCCS vs. MCO level

Core Functions	Responsible Entity
1. Developing and submitting recommendations for drug list	AHCCCS
2. Suggest clinical prior authorizations on outpatient prescription drugs	DBHS, MCO Exceptions: AHCCCS- HCV, Tobacco Cessation
3. Recommend educational interventions for Medicaid providers	MCO
4. Review drug utilization	MCO

AHCCCS Drug List Overview

- Implemented Oct 2012 to assist providers in navigating AHCCCS pharmacy benefit
- Specifies which drugs:
  - Are preferred agents
  - Require step therapy
  - Require PA to ensure clinically appropriate medication use
  - Have QL
- Meds not listed on the AHCCCS Drug List are available through PA

Medicaid Drug Lists

AHCCCS Drug List

1. Managed by AHCCCS
2. Applies to all lines of business (acute, ALTCS, CRS, RBHA)
3. Contains supplemental rebate classes
4. PA criteria developed by MCOs*

Behavioral Health Drug List

1. Managed by DBHS
2. Applies to RBHAs
3. No supplemental rebate classes currently
4. All PA criteria developed by DBHS through P&T

Supplemental Rebate Overview

- 47 states and DC participate in single and/or multi-state arrangements
  - Arizona most recently added Jan 2015

AHCCCS Drug List Overview: Current Supplemental Classes

1. HCV (Jan 2015)
2. Epinephrine, Inj. (Nov 2015)
3. Cytokine and CAM Antagonists (Nov 2015)
4. Growth hormone (Nov 2015)
5. Inhaled Antibiotics (Nov 2015)
6. Inhaled Glucocorticoids (Feb 2016)

AHCCCS Drug List: Current Preferred Agents

Drug Class	Preferred Agents	PA Required
HCV	Harvoni Sovaldi	Yes Yes
Inhaled Antibiotics	Bethkis Kitabis	Yes Yes
Cytokine and CAM Antagonists	Humira Enbrel	Yes Yes
Growth Hormone	Norditropin Nutropin AQ Genotropin	Yes Yes Yes
Epinephrine, Inj.	Epi-Pen Jr Epi-Pen	For >2 per month For >2 per month

Supplemental Rebates

- Contractors shall approve preferred drugs for medication classes listed in the AHCCCS Drug List before considering approval of non-preferred drugs.
- However, Contractors shall approve non-preferred drugs when:
  - The member has previously completed step therapy using the preferred drug(s) or
  - The member's prescribing clinician supports the medical necessity of the non-preferred drug over the preferred drug for the particular member.

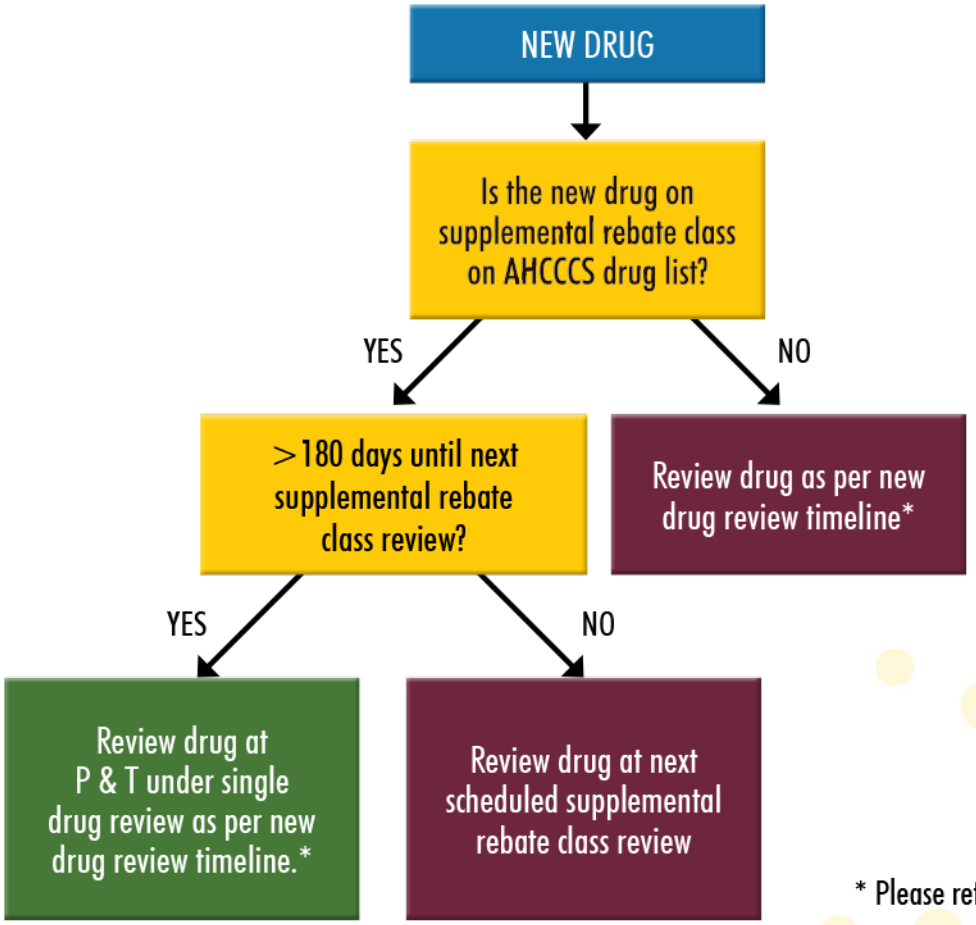
Supplemental Rebates: Effective Dates

- First day of the quarter following meeting
- Effective date of the preferred status for drugs approved at 11-17-15 mtg is 1-1-16

Supplemental Rebates: Grandfathering Policy

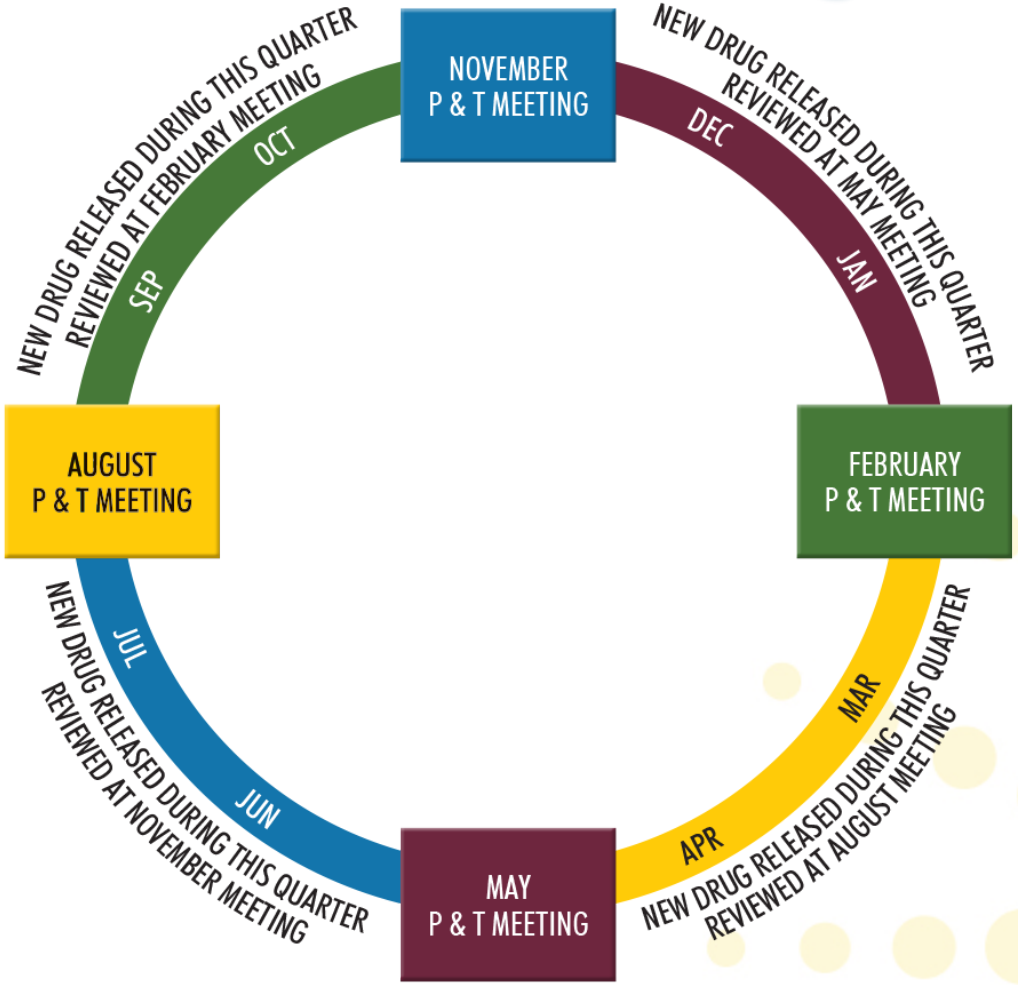
- Grandfathering of non-preferred drugs refers to the continued coverage of non-preferred drugs that members are currently utilizing without a trial of the preferred drug(s) on the AHCCCS Drug List.
- The P&T shall make recommendations on the grandfathering status of each non-preferred drug for each therapeutic class reviewed

Process for New Drug Reviews



* Please refer to new drug review timeline

Timeframes for New Drug Reviews



Supplemental Rebate Class Review: Glucocorticoids Inhaled

Rick Pope, PharmD

Magellan Medicaid Administration

Glucocorticoids, Inhaled

Class Overview

- The inhaled glucocorticoid class includes:
  - Single agent glucocorticoid products indicated for the management of asthma, e.g. budesonide (Pulmicort)
  - Combination glucocorticoid products including a long-acting bronchodilating agent that are indicated for either both COPD and asthma, or asthma alone
    - Advair Diskus (fluticasone/salmeterol)
    - Advair HFA (fluticasone propionate/salmeterol)
    - Breo Ellipta (fluticasone furoate/vilanterol)
    - Dulera (mometasone/formoterol)
    - Symbicort (budesonide/formoterol)

Glucocorticoids, Inhaled

New Product in Class: Arnuity Ellipta (fluticasone furoate)

- Indicated for once-daily maintenance treatment of asthma in patients 12 years and older
- Contraindications, warnings, adverse effects, and drug interactions are similar to those for other inhaled glucocorticoids
- It is in pregnancy category C
- Arnuity Ellipta is given as one inhalation daily
- It is available as 100 or 200 mcg powder for inhalation

Glucocorticoids, Inhaled

Fluticasone furoate (Arnuity Ellipta) versus fluticasone propionate (Flovent Diskus)

- 343 patients with asthma not controlled by their current ICS therapy, received fluticasone furoate (100 mcg) once daily, placebo once daily, or twice daily administered fluticasone propionate (250 mcg).
- At week 24, once daily fluticasone furoate and twice daily fluticasone propionate significantly improved pre-dose evening FEV1 (+146 mL; p=0.009) compared with placebo (+145 mL; p=0.011)
- The secondary endpoint of percentage rescue-free 24-hour periods, was increased with fluticasone furoate (+14.8%; p<0.001) and fluticasone propionate (+17.9%; p<0.001) compared to placebo

Glucocorticoids, Inhaled

Fluticasone furoate/vilanterol (Breo Ellipta) versus fluticasone furoate (Arnuity Ellipta)

- Two 12-week randomized, double-blind, parallel-group trials with subjects with asthma not controlled on their current treatments of ICS or ICS/LABA
- In study 1, 609 patients were randomized to fluticasone furoate/vilanterol 100/25 mcg, fluticasone furoate 100 mcg, or placebo.
  - At week 12, change from baseline in weighted mean FEV1 was significantly greater for fluticasone furoate/vilanterol 100/25 mcg compared with placebo (302 mL; 95% CI, 178-426; $p<0.001$)
  - Change from baseline in weighted mean FEV1 for fluticasone furoate/vilanterol 100/25 was numerically greater than fluticasone furoate 100 mcg, but not statistically significant (116 mL; 95% CI, -5-236).

Glucocorticoids, Inhaled

Fluticasone furoate/vilanterol (Breo Ellipta) versus fluticasone furoate (Arnuity Ellipta)

- Change from baseline in trough FEV1 was significantly greater for fluticasone furoate/vilanterol 100/25 compared with placebo (172 mL; 95% CI, 87-258; p<0.001)
- Change from baseline in trough FEV1 for fluticasone furoate/vilanterol 100/25 mcg was numerically greater than fluticasone furoate 100 mcg, but not statistically significant (36 mL; 95% CI, -48-120).

- In study 2, 1,039 patients were randomized to fluticasone/vilanterol 100/25 mcg, fluticasone/vilanterol 200/25 mcg, or fluticasone furoate 100 mcg.
  - The change from baseline in weighted mean FEV1 (0 to 24 hours) was significantly greater for fluticasone /vilanterol 100/25 mcg compared with fluticasone furoate 100 mcg (108 mL; 95% CI, 45-171; p<0.001) at week 12.

Glucocorticoids, Inhaled

Fluticasone furoate/vilanterol (Breo Ellipta) versus fluticasone propionate (Flovent Diskus) and fluticasone furoate (Arnuity Ellipta)

- 24-week randomized, double-blind, parallel-group trial
- Patients (n=586) not controlled on their current treatments of ICS or ICS plus a LABA were randomized to fluticasone furoate/vilanterol 200/25 mcg, fluticasone furoate 200 mcg, or fluticasone propionate 500 mcg
- The change from baseline in weighted mean FEV1 (0 to 24 hours) was significantly greater for fluticasone furoate/vilanterol 200/25 mcg compared with fluticasone furoate 200 mcg (136 mL; 95% CI, 1-270; p=0.048) at week 24.
- The change from baseline in trough FEV1 was significantly greater for fluticasone furoate/vilanterol 200/25 mcg compared with fluticasone furoate 200 mcg (193 mL; 95% CI, 108-277; p<0.001) at week 24.

Glucocorticoids, Inhaled

Fluticasone furoate/vilanterol (Breo Ellipta) versus fluticasone propionate (Flovent Diskus) and fluticasone furoate (Arnuity Ellipta)

- Patients receiving fluticasone furoate/vilanterol 200/25 mcg had significantly greater improvements from baseline in percentage of 24-hour periods without need of beta2-agonist rescue medication use and percentage of 24-hour periods without asthma symptoms compared with patients receiving fluticasone furoate 200 mcg.

Glucocorticoids, Inhaled

Product Updates:

- Asmanex is now available with an HFA propellant
- Breo Ellipta is now indicated for once daily treatment of asthma in adults (previously indicated only for COPD maintenance treatment and exacerbation reduction)

Glucocorticoids, Inhaled

Guideline Updates:

- The 2015 update to the GOLD guidelines Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines did not contain any significant changes to recommendations for drug therapy. (February 2015)
- The 2015 update to the GINA Global Strategy for Asthma Management and Prevention guidelines did not contain any significant changes to recommendations for first-line drug therapy. (April 2015)

Executive Session

Recommendations: Preferred products Glucocorticoids Inhaled

- Combination Products:
  - Dulera
  - Advair Diskus
  - Symbicort
- Single Agent Products:
  - Asmanex
  - Qvar
  - Flovent HFA
  - Pulmicort 0.25, 0.5 mg, 1 mg respules
- Age Edit for Advair HFA: 4 to 12 years old
- No Grandfathering

Anxiolytic Proposed Quantity Limits

Suzi Berman, RPH

Anxiolytic / Benzodiazepine Proposed Quantity Limits

- A workgroup was assembled to evaluate the quantity limits for the anxiolytic drug class, which includes benzodiazepines and non-benzodiazepines, to address safety concerns and reduce the potential for misuse.
- The current quantity limit for all anxiolytics on the AHCCCS Drug List is 120 units per month.
- The Workgroup evaluated the following:
  - FDA maximum allowed daily dosages for each product.
  - The average quantity per drug/month to suggested quantities by the workgroup.
  - Considered the dosing for specialty products.

Benzodiazepine Proposed Quantity Limits

- Committee Discussion
- Committee Vote

AHCCCS
Arizona Health Care Cost Containment System

Drug List Change Requests

Suzi Berman, RPH
AHCCCS Pharmacy Director

Managed Care Contractors' Drug List Change Requests

Lidocaine Ointment 5%

- A topical anesthetic
- Request is to prior authorize treatment to limit it to the FDA indication due to cost stating $5.68 – 6.56 per gram stating the drug is being used to treat arthritis and neuropathy.
- AHCCCS FY15 utilization data reports the average cost at $3.93 per gram
- AHCCCS Medical Policy Manual Pharmacy Policy 310-V states: Prior authorization requests submitted for review must be evaluated for clinical appropriateness based on the strength of the scientific evidence and standards of practice.

Lidocaine Change Request cont'd

- Lidocaine is not FDA approved to treat neuropathic pain but is a recommendation on treatment guidelines.
- Per UpToDate: The initial treatment of neuropathic pain involves either tricyclic and dual-acting antidepressants or gabapentin/pregabalin, with adjunctive topical therapy (eg, topical lidocaine) when pain is localized.
- Committee Discussion and Vote

Managed Care Contractors' Drug List Change Requests

Benicar (olmesartan)

- An angiotensin II receptor blocker (ARB)
- Many cardiovascular uses
- Request is to remove Benicar from the drug list due to cost.

Benicar Strength	Prescription Count	MCO Reported Cost	FY15 Average Cost Reported to AHCCCS
5mg	153	$4.19- 4.33	$3.57
20mg	748	$5.11 - $5.20	$4.22
40mg	1074	$7.09 - $7.36	$5.84

Benicar Change Request cont'd

- US Patent expires April 26, 2016
- Other ARBs on the AHCCCS Drug List:

Brand Name	Generic Name	Step Therapy Requirements on the Drug List	Approximate Cost per Unit
Avapro	Irbesartan	None	$0.38 - $0.59
Cozaar	Losartan	None	$0.18 - $0.34
Valsartan	Diovan	None	$1.78 - $2.51
Benicar	Olmesartan	2-steps: Losartan Irbesartan	$3.57 - $5.84

- Committee Discussion and Vote

Managed Care Contractors' Drug List Change Requests

Qualaquin (quinine)

- Request is to limit coverage to the FDA approved indication of malaria due to cost: $6.26 per unit
- Off label use for nocturnal leg cramps.
- Black box warning when used for nocturnal leg cramp
- FY15 utilization for quinine: 63 prescriptions
- Average cost per capsule: $4.77 per unit
- Committee Discussion and Vote

Managed Care Contractors' Drug List Change Requests

Ciprodex (ciprofloxacin/dexamethasone) Otic

- Approved for otitis media and externa ear infections
- Request to remove Ciprodex from the drug list due to cost: $169.65 per Unit

DRUG	FY15 Average Cost	FY15 Rx Count
Ciprodex	$165.22	9243
Cipro HC	$215.24	1839
Cortisporin TC	$124.82	56
Neomycin Polymyxin HC 1%	$23.54	6710

- Committee Discussion and Vote

Managed Care Contractors' Drug List Change Requests

Nystatin/Triamcinolone Ointment/Cream

- Request is to remove the combination product from the drug list due to cost.
- Both medication are available at significantly lesser costs when dispensed as separate prescriptions.
- MCO reported average cost: $4.46 - $5.23 per gram
- AHCCCS FY15 Utilization Average Cost:
  - $3.66 per gram for the combination product
  - $0.60 per gram for Nystatin
  - $0.15 per gram for Triamcinolone
- Committee Discussion and Vote

New Drug Reviews

Rick Pope, PharmD
Magellan

Suzi Berman
AHCCCS

New Product Reviews: Non-Supplemental Rebate Classes

- Entresto (sacubitril/valsartan)
- Envarsus XR (tacrolimus)
- Odomzo (sonidegib)
- Orkambi (Lumacaftor-Ivacaftor)
- Praluent (alirocumab)
- Repatha (evolocumab)
- Tresiba (insulin degludec)
- Varubi (rolapitant)
- Vivlodex (meloxicam)
- Zarxio (filgrastim-sndz)
- Zecuity (sumatriptan)

New Product Reviews: Non-Supplemental Rebate Classes

- These products are not listed on the AHCCCS Drug List but are available through prior authorization
- P&T will make recommendations on whether or not to add to AHCCCS Drug List

New Product Reviews: Non-Supplemental Rebate Class

Parameters to consider re: adding new drug to non-supplemental rebate class on AHCCCS Drug List:

1. New drug more efficacious than current listed drugs
2. New drug safer than current listed drugs
3. New drug has different mechanism of action than current listed drugs
4. New drug more cost effective than current listed drugs

Entresto (sacubitril/valsartan)

- Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.
- Contraindicated with patient history of angioedema related to ACEI/ARB therapy, concomitant use with ACEIs (use with ARBs should also be avoided, but this is not listed as a contraindication), and concomitant use with Tekturna in diabetic patients
- Black box warning for fetal toxicity. Other warnings include angioedema, hypotension, and monitoring renal function

Entresto (sacubitril/valsartan)

- Drug interactions include use with potassium-sparing diuretics (increased potassium) and NSAIDs (risk of renal impairment)
- Hypotension, hyperkalemia, cough, dizziness, and renal failure are the most common adverse effects
- Entresto is given twice daily and is available in 24/26, 49/51, and 97/103 mg tablets. Dose reductions are recommended in patients with severe renal impairment or moderate hepatic impairment; use in severe hepatic impairment is not recommended.

AHCCCS New Drug Recommendations

Entresto (sacubitril/valsartan)

- New drug class to treat heart failure with reduced ejection fraction.
- Angiotensin Receptor Neprilysin Inhibitor Class
- Decreased Mortality Rates: Approximately 20% when compared to enalapril.
- Angiotensin converting enzyme inhibitors (ACE Inhibitors) and Angiotensin II Receptor Blockers (ARBs) currently used in treatment.
- Recommendation is to add Entresto, because of improved outcomes, to the AHCCCS Drug List under Cardiovascular Agents-Misc with a prior authorization requirement.

Envarsus XR (tacrolimus)

- Indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release in combination with other immunosuppressants.
- Black box warning regarding increased risk of serious infections and malignancies.
- Other warnings include new onset diabetes, nephrotoxicity, neurotoxicity including posterior reversible encephalopathy syndrome, and hyperkalemia.

Envarsus XR (tacrolimus)

- Co-administration of CYP 3A inducers with Envarsus XR increase the risk of graft rejection; CYP 3A inhibitors increase the risk of serious adverse events with Envarsus XR.
- Diarrhea and increased blood creatinine are the most common adverse effects.
- It is in pregnancy category C.
- Envarsus XR is given once daily on an empty stomach, preferably in the morning.

Envarsus XR (tacrolimus)

- Administer 80% of the pre-conversion dose of tacrolimus IR.
- Patients with moderate to severe hepatic impairment should not take Envarsus XR.
- It is available in 0.75, 1, and 4 mg extended-release tablets.

AHCCCS New Drug Recommendations

Envarsus XR (tacrolimus)

- New long-acting product of tacrolimus, an immunosuppressive.
- Tacrolimus immediate and long-acting agents are currently listed on the AHCCCS Drug List.
- Recommendation is to not add Envarsus XR to the AHCCCS Drug List because an extended release formulation is currently available on the drug list and is more cost effective.

Odomzo (sonidegib)

- Indicated for the treatment of adults with locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.
- There is a black box warning for embryo-fetal death or severe birth defects.
- Warnings include musculoskeletal adverse effects and suggestions against blood donation during treatment or 20 months afterward.

Odomzo (sonidegib)

- Should be avoided with concurrent administration of strong or moderate CYP3A inhibitors or inducers.
- Muscle spasms, alopecia, dysgeusia, fatigue, nausea, and musculoskeletal pain are the most common adverse effects.
- Odomzo is given once daily on an empty stomach.
- It is available as 200 mg capsules

AHCCCS New Drug Recommendations

Odomzo (sonidegib)

- New anti-cancer drug (antineoplastics).
- Approved to treat basal cell carcinoma.
- Approved for use after surgery/radiation.
- Recommendation is to not add the drug to the AHCCCS Drug List. Odomzo is available through the prior authorization process.
- A subcommittee will review antineoplastics at a later date.

Orkambi (Lumacaftor-Ivacaftor)

- Indicated for the treatment of CF in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene.
- No contraindications are listed in the prescribing information.
- Pregnancy Category B.
- Lumacaftor-ivacaftor should be used with caution in patients with advanced liver disease only if the benefits are expected to outweigh the risks.
- Available as a lumacaftor 200mg/ivacaftor 125 mg tablet

Orkambi (Lumacaftor-Ivacaftor)

- The recommended dose for adults and pediatric patients age 12 years and older is two tablets taken every 12 hours with fat-containing food (e.g., a typical CF diet).
  - In patients with moderate or severe hepatic impairment, dose reduction is recommended to two tablets in the morning and one tablet in the evening for moderate hepatic impairment and one tablet every 12 hours for severe hepatic impairment.
  - When initiating lumacaftor-ivacaftor in patients taking strong CYP3A inhibitors, lumacaftor-ivacaftor dose should be reduced for the first week of treatment until steady state is reached.

Orkambi (Lumacaftor-Ivacaftor)

- The most common adverse reactions in studies were dyspnea, nasopharyngitis, nausea, diarrhea, upper respiratory tract infection, fatigue, respiration abnormality, blood creatine phosphokinase increase, rash, flatulence, rhinorrhea, and influenza.

Orkambi (Lumacaftor-Ivacaftor)

- Elevated transaminases (ALT/AST) have been observed, in some cases associated with elevated bilirubin.
- Serum transaminases and bilirubin should be measured before initiating lumacaftor-ivacaftor and monitored every three months during the first year of treatment, and annually thereafter.
- For patients with a history of ALT, AST, or bilirubin elevations, more frequent monitoring should be considered.

AHCCCS New Drug Recommendations

Orkambi (lumacaftor-ivacaftor)

- New combination drug to treat cystic fibrosis.
- Specific to patients with two copies of the F508del mutation.
- Recommendation is to not add Orkambi to the AHCCCS Drug List.
- Orkambi is available through the prior authorization process.
- Medications for cystic fibrosis will be reviewed as a class at later date.

Praluent (alirocumab)

- First PSCK9 inhibitor to market
- Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional LDL lowering
- Warnings include hypersensitivity reactions that may require hospitalization
- There are no clinically significant drug interactions.

Praluent (alirocumab)

- Nasopharyngitis, injection site reactions, and influenza are the most common adverse effects.
- There are no data available in pregnant women to inform a drug-associated risk.
- Praluent is given subcutaneously once every two weeks.
- It is available as 75 and 150 mg prefilled pens and syringes.
- Praluent should be stored in the refrigerator.

Repatha (evolocumab)

- Second PSCK9 inhibitor to market
- Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional LDL lowering; and as an adjunct to diet and other LDL-lowering therapies in patients with homozygous familial hypercholesterolemia who require additional LDL lowering

Repatha (evolocumab)

- There are no clinically significant drug interactions.
- Nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions are the most common adverse effects.
- There are no data available in pregnant women to inform a drug-associated risk.
- Warnings include allergic reactions such as rash and urticaria.

Repatha (evolocumab)

- Repatha is given subcutaneously once every two weeks (140 mg) or once a month (420 mg); the HoFH indication is supported by only the monthly dosing option.
- It is available as 140 mg prefilled auto-injectors and syringes.
- Repatha should be stored in the refrigerator.

AHCCCS New Drug Recommendations

Praluent (alirocumab) and Repatha (evolocumab)

- New class of drugs referred to as PSCK9s which are human monoclonal antibodies.
- Approved to treat hyperlipidemia.
- Treatment is approximately $14K annually.
- Recommendation is to not add either drug to the AHCCCS drug list because there are other more cost effective medications on the AHCCCS Drug List.
- The PSCK9 class will be reviewed at a later date.

Tresiba (insulin degludec)

- Indicated to improve glycemic control in adults with diabetes.
- Contraindicated during episodes of hypoglycemia
- Warnings include hypoglycemia or hyperglycemia with changes in insulin regimens, hypoglycemia, hypersensitivity reactions, and hypokalemia.
- There may be drug interactions when given with drugs that affect glucose metabolism.
- Signs and symptoms of hypoglycemia may be reduced or absent when used with adrenergic blockers.

Tresiba (insulin degludec)

- Hypoglycemia, allergic reactions, and injection site reactions are the most common adverse effects.
- There are no clinical studies with Tresiba in pregnant women.
- Tresiba is given subcutaneously once daily at an individualized dose.
- It is available in a 100 and 200 U/mL FlexTouch prefilled pen (3 mL).

AHCCCS New Drug Recommendations

Tresiba

- New once-daily insulin.
- The AHCCCS Drug List contains other long acting insulins that can be dosed daily.
- All are less costly to the AHCCCS due to the federal rebate.
- Recommendation is to not add Tresiba to the AHCCCS Drug List because the current insulins listed on the drug list are more cost effective.

Varubi (rolapitant)

- Indicated in combination with other antiemetics for the prevention of delayed nausea/vomiting associated with initial and repeat courses of emetogenic chemotherapy in adults including, but not limited to, highly emetogenic chemotherapy.
- Use with thioridazine is contraindicated.
- Warnings include drug interactions with CYP 2D6 substrates with narrow therapeutic indices.
- Other drug interactions include BCRP and p-glycoprotein substrates with narrow therapeutic indices and strong CYP 3A4 inducers.

Varubi (rolapitant)

- Neutropenia, hiccups, decreased appetite, and dizziness are the most common adverse effects.
- There are no data available in pregnant women to inform a drug-associated risk.
- Varubi is given one to two hours prior to the start of chemotherapy in combination with dexamethasone and a 5-HT3 antagonist.
- Use should be avoided in patients with severe hepatic impairment.
- It is available in 90 mg tablets.

AHCCCS New Drug Recommendations

Varubi (rolapitant)

- New addition to the antiemetic class- *Substance P/Neurokinin 1 (NK1) Receptor Antagonist*
- Approved for the prevention of chemotherapy induced nausea and vomiting in conjunction with other antiemetics.
- Long-acting, approximately 14 days.
- Recommendation is to not add Varubi to the AHCCCS Drug List, because other antiemetic medications on the Drug List are more cost effective.
- Varubi is available through the prior authorization process.

Vivlodex (meloxicam)

- Indicated for the management of osteoarthritis pain.
- Contraindications, warnings, adverse effects, and drug interactions are similar to those for other meloxicam product.
- Vivlodex is given once daily and is available as 5 and 10 mg capsules.
- Vivlodex is not interchangeable with other formulations of meloxicam even if the dose is the same.

AHCCCS New Drug Recommendations

Vivlodex (meloxicam)

- A non-steroidal anti-inflammatory agent (NSAIDs).
- Remake of an older drug, meloxicam, that is currently on the AHCCCS Drug List.
- Recommendation is to not add Vivlodex to the AHCCCS Drug List. Meloxicam and other current available NSAIDs on the AHCCCS Drug List are more cost effective.

Zarxio (filgrastim-sndz)

- First FDA-approved biosimilar product.
- The reference product for filgrastim-sndz is Amgen's filgrastim (Neupogen).
- In general, NCCN recommends filgrastim-sndz in the same instances as filgrastim; however, they do not recommend switching between biosimilars and their corresponding reference products during treatment.
  - The use of filgrastim in mobilization of allogeneic donors (unapproved indication) carries a 2A recommendation, while filgrastim-sndz carries a 2B recommendation.

Zarxio (filgrastim-sndz)

Indicated for:

- Decreasing the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs
- Reducing the time to neutrophil recovery and duration of fever following induction or consolidation chemotherapy in patients with acute myeloid leukemia
- Reducing the duration of neutropenia and related sequelae in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant
- Mobilizing autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- Reducing the incidence and duration of sequelae of severe neutropenia in symptomatic patients with congenital, cyclic, or idiopathic neutropenia.

Zarxio (filgrastim-sndz)

- Contraindications, warnings, adverse effects, and drug interactions are similar to those for Neupogen.
- Zarxio is given as 5-10 mcg/kg/day subcutaneously (or intravenously, depending on the indication) and comes in 300 and 480 mcg single-dose prefilled syringes.

AHCCCS New Drug Recommendations

Zarxio (filgrastim-sndz)

- A new biosimilar for Neupogen 300mcg & 480mcg
- Both drugs are similar in efficacies.
- AHCCCS Policy 310-V: Contractors shall not transition to a biosimilar drug until AHCCCS has determined that the biosimilar drug is overall more cost-effective to the state than the continued use of the brand name drug.
- Recommendation is to not add Zarxio to the AHCCCS Drug List because the net cost to AHCCCS is more costly than the brand name, Neupogen.

Zecuity (sumatriptan)

- Indicated for the acute treatment of migraine with or without aura in adults.
- Contraindicated in history of coronary artery disease or coronary vasospasm; Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; recent use of another triptan or ergotamine-containing medication; MAO inhibitor use in the past two weeks; severe hepatic impairment; and allergic contact dermatitis to Zecuity components

Zecuity (sumatriptan)

- Warnings include removal of Zecuity before MRI procedures (due to metal in batteries), myocardial infarction and Prinzmetal's angina, and other cardiac disorders.
- Application site pain, paresthesia, pruritus, and warmth are the most common adverse effects.
- It is in pregnancy category C

Zecuity (sumatriptan)

- It is available as a iontophoretic transdermal system that delivers 6.5 mg over four hours
- It is administered to the upper arm or thigh at headache onset. A second system may be applied no sooner than two hours following the first; only two systems should be used in a 24-hour period.
- System details include administration within 15 minutes of assembly initiation and an activation button once the system is applied.

AHCCCS New Drug Recommendations

Zecuity (Sumatriptan)

- New 4-hour transdermal antimigraine patch delivering 6.5mg of sumatriptan.
- Sumatriptan tablets, nasal spray and injection are currently available on the AHCCCS Drug List.
- Very high cost in comparison to current Sumatriptan products and other triptans on the AHCCCS Drug List.
- Recommendation is to not add Zecuity to the AHCCCS Drug List because the current available anti-migraine products on the AHCCCS Drug List are more cost effective

BH Drug List

Sara Salek

BH Drug List

- AHCCCS now managing BH Drug List
- Stakeholder feedback re: Substance Abuse Meds
- Next Steps

Next Meeting Scheduled for May 17, 2016