310-V - PRESCRIPTION MEDICATIONS/PHARMACY SERVICES

EFFECTIVE DATES: 10/01/94, 01/01/18, 10/01/18, 07/19/19, 09/01/20, 10/01/21, 10/01/23, 05/20/24

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I. PURPOSE

This Policy applies to ACC, ACC-RBHA, ALTCS E/PD, DCS/CHP (CHP), and DES/DDD (DDD) Contractors; and Fee-For-Service (FFS) Programs including: the American Indian Health Program (AIHP), DES/DDD Tribal Health Program (DDD/THP), Tribal ALTCS, TRBHA, and all FFS populations, excluding Federal Emergency Services (FES). (For FES, refer to AMPM Chapter 1100). The purpose of this Policy is to specify medication, device, and pharmacy coverage requirements and limitations of the AHCCCS pharmacy benefit.

II. DEFINITIONS

For purposes of this Policy, the following terms are defined as:

340B CEILING PRICE	The maximum price that drug manufacturers may charge covered entities participating in the 340B Drug Pricing Program as reported by the drug manufacturer to the United States Department of Health and Human Services. The 340B Ceiling Price per unit is defined as the Average Manufacturer Price minus the Federal Unit Rebate Amount.
340B CONTRACTED PHARMACIES	A separate pharmacy that a 340B covered entity contracts with to provide and dispense prescription and physician-administered drugs using medications that are subject to 340B drug pricing program.
340B COVERED ENTITY	An organization as defined by 42 United States Code section 256b that participates in the 340B drug pricing program.
340B DRUG PRICING PROGRAM	The discount drug purchasing program described in section 256b of 42 United States Code.
ACTUAL ACQUISITION COST	The purchase price of a drug paid by a pharmacy net of all discounts, rebates, chargebacks, and other adjustments to the price of the drug, not including professional fees.
ADVERSE DRUG EVENT (ADE)	An injury resulting from medical intervention related to a drug including harms that occur during medical care that are directly caused by the drug including but not limited to medication errors, adverse drug reactions, allergic reactions, and overdose.

AHCCCS DRUG LIST	A list of Federally and State reimbursable behavioral health and physical health care medications and medical devices that is to be used by AHCCCS FFS Programs and all Contractors responsible for the administration of acute and long-term care pharmacy benefits. This drug list identifies specific Federally and State reimbursable medications and related products, which are supported by current evidence-based medicine. The AHCCCS Drug List includes preferred drugs and was developed to encourage the use of safe, effective, clinically appropriate, and the most cost-effective medications.
AVERAGE MANUFACTURER PRICE (AMP)	The average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts.
BIOSIMILAR	A biological drug approved by the FDA based on a showing that it is highly similar to an FDA-Approved biological drug, known as the reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.
CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)	The Federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid.
CHRONIC INTRACTABLE PAIN	As specified in A.R.S. § 32-3248.01, meets both of the following: 1. The pain is excruciating, constant, incurable and of such severity that it dominates virtually every conscious moment, and 2. The pain produces mental and physical debilitation.
FEDERAL SUPPLY SCHEDULE (FSS)	The collection of multiple award contracts used by Federal agencies, U.S. territories, Indian tribes, and other specified entities to purchase supplies and services from outside vendors. FSS prices for the pharmaceutical schedule are negotiated by the VA and are based on the prices that manufacturers charge their “most-favored” non-Federal customers under comparable terms and conditions.
GENERIC DRUG	A drug that contains the same active ingredient(s) as a brand name drug and the FDA has approved it to be manufactured and marketed after the brand name drugs patent expires. Generic drug substitution shall be completed in accordance with Arizona State Board of Pharmacy rules and regulations.

MEDICAL DEVICE	Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including a component part, or accessory which is: 1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, 2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals or, 3. Intended to affect the structure or any function for the body of man or other animals, and which does not achieve it primary intended purposes through chemical action within or on the body of man or other animals, and 4. Which does not achieve it primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device": does not include software functions excluded pursuant to Section 520(o).
MEDICATION ERROR	The Federal Drug Administration (FDA) defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare provider, patient, or consumer.
NOMINAL PRICE	A drug that is purchased for a price that is less than 10% of the Average Manufacturer Price in the same quarter for which the AMP is computed.
NON-PREFERRED DRUG	A medication that is not listed on the AHCCCS Drug List. Non-preferred drugs require prior authorization.
NON-PREFERRED DEVICE	A medical device that is not listed on the AHCCCS Drug List. Non-preferred medical devices require Prior Authorization (PA).
PHARMACY AND THERAPEUTICS (P&T) COMMITTEE	The advisory committee to AHCCCS, which is responsible for developing, managing, updating, and administering the AHCCCS Drug List. The P&T Committee is primarily comprised of physicians, pharmacists, nurses, other health care professionals and community members.
PREFERRED DRUG	A medication that has been clinically reviewed and approved by the AHCCCS P&T Committee for inclusion on the AHCCCS Drug List as a preferred drug due to its proven clinical efficacy and cost effectiveness.
PROFESSIONAL FEE	The amount paid for the professional services provided by the pharmacist for dispensing a prescription. The Professional Fee does not include any payment for the drug being dispensed.

STANDING ORDER	An AHCCCS Registered Prescriber's order that can be exercised by other health care workers for a member that meets the designated criteria by the prescribing provider.
STEP THERAPY	The practice of initiating drug therapy for a medical condition with the most cost-effective and safe drug and stepping up through a sequence of alternative drug therapies if the preceding treatment option fails.
USUAL & CUSTOMARY PRICE (U&C)	The dollar amount of a pharmacy's charge for a prescription to the general public, a special population, or an inclusive category of customers that reflects all advertised savings, discounts, special promotions, or other programs including membership-based discounts.

Additional definitions are located on the AHCCCS website at: AHCCCS Contract and Policy Dictionary.

III. POLICY

AHCCCS and its Contractors shall cover medically necessary, cost-effective and Federally and State reimbursable medications and devices for members as prescribed and/or administered by a physician, physician's assistant, nurse practitioner, dentist, or other AHCCCS registered practitioner with prescriptive authority in the State of Arizona and dispensed by an AHCCCS registered licensed pharmacy pursuant to 9 A.A.C. 22 Article 2, 9 A.A.C. 28 Article 2, and 9 A.A.C. 31 Article 2, and for persons with a Serious Mental Illness (SMI) designation, pursuant to A.R.S. § 36-550.

Mental Health Block Grant (MHBG) provisions shall apply to Children with Serious Emotional Disturbance (SED), individuals in First Episode Psychosis (FEP), and adults with an SMI designation. For Individuals with a Substance Use Disorder (SUD), Substance Use Block Grant (SUBG) provisions shall apply. Refer to AMPM Policy 320-T1 for additional requirements.

A. THE AHCCCS DRUG LIST

The AHCCCS Pharmacy and Therapeutics (P&T) Committee is responsible for developing, managing, and updating the AHCCCS Drug List to assist providers in selecting clinically appropriate and cost-effective drugs or a devices for AHCCCS members. Refer to ACOM Policy 111.

Each Contractor is required to maintain its own drug list to meet the unique needs of the members they serve. At a minimum, the Contractor's drug list shall include all the drugs listed on the AHCCCS Drug List as further detailed below.

The AHCCCS Drug List is not an all-inclusive list of medications for AHCCCS members. The Contractor and FFS Programs are required to cover *all* medically necessary, clinically appropriate, and cost-effective medications that are Federally and State reimbursable regardless of whether or not these medications are included on this list.

1. Preferred Drugs

   The AHCCCS Drug List designates medications that are Preferred Drugs for specific therapeutic classes. The Contractor is required to maintain Preferred Drug lists that include each and every drug exactly as listed on the AHCCCS Drug List. When the AHCCCS Drug List specifies a Preferred Drug(s) in a particular therapeutic class, The Contractor is not permitted to add other Preferred Drugs to their Preferred Drug lists in those therapeutic classes.

   The Contractor and FFS Programs shall inform their Pharmacy Benefit Managers (PBM) of the Preferred Drugs and shall require the PBM to institute point-of-sale edits that communicate back to the pharmacy the **Preferred Drug(s) of a therapeutic class whenever a claim is submitted for a Non-Preferred Drug**. Preferred Drugs recommended by the AHCCCS P&T Committee and approved by AHCCCS are effective on the first day of the first month of the quarter following the P&T Meeting unless otherwise communicated by AHCCCS.

   The Contractor and FFS Programs shall approve the Preferred Drugs listed for the therapeutic classes contained on the AHCCCS Drug List, as appropriate, before approving a Non-Preferred Drug unless:
   a. The member has previously completed Step Therapy using the Preferred Drug(s), or
   b. The member's prescribing clinician provides documentation supporting the medical necessity of the Non-Preferred Drug over the Preferred Drug for the member.

   The Contractor shall not disadvantage one preferred drug over another preferred drug when AHCCCS has approved preferred drugs and/or supplemental rebates for a therapeutic class. PA criteria may not require a trial and failure of one preferred agent when there are others that are also preferred and have the same indication.

2. The Contractor is not required to provide a Notice of Adverse Benefit Determination (NOA) when the prescribing clinician is in agreement with the change to the Preferred Drug. A Prior Authorization (PA) request may be submitted for the Non-Preferred Drug when the prescribing clinician is not in agreement with transition to the Preferred Drug. The Contractor shall issue an NOA in accordance with ACOM Policy 414 for service authorizations when a PA request is denied or a previously approved authorization is terminated, suspended, or reduced.

3. Grandfathering of Non-Preferred Drugs

   Grandfathering of Non-Preferred Drugs refers to the continued authorization of Non-Preferred Drugs for members who are currently utilizing Non-Preferred Drugs without having completed Step Therapy of the Preferred Drug(s) on the AHCCCS Drug List, as appropriate.

   The AHCCCS P&T Committee shall make recommendations to AHCCCS on the grandfathering status of each Non-Preferred Drug for each therapeutic class reviewed by the committee. AHCCCS shall communicate to its Contractors the Non-Preferred Drugs that have been approved for grandfathering. The Contractor is required to grandfather members on these medications.

4. Prior Authorization (PA)

   The AHCCCS Drug List specifies which medications require PA prior to dispensing the medication.

   The Contractor and FFS Programs may establish PA criteria based on clinical appropriateness, scientific evidence, and standards of practice that include, but are not limited, to all of the following:
   a. Food and Drug Administration (FDA) approved indications and limits,
   b. Published practice guidelines and treatment protocols,
   c. 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,
   d. Drug Facts and Comparisons,
   e. American Hospital Formulary Service Drug Information,
   f. United States Pharmacopeia – Drug Information,
   g. DRUGDEX Information System,
   h. UpToDate,
   i. MicroMedex,
   j. Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies, and
   k. Other drug reference resources

All Federally and State reimbursable drugs that are not listed on the AHCCCS Drug List or the Contractor's drug lists shall be available through the PA process.

A Federally and State reimbursable medication shall not be denied solely due to the lack of an FDA indication. Off-Label prescribing may be clinically appropriate as outlined and evidenced by a. through k. above.

The Contractor is prohibited from adding PA and/or Step Therapy requirements to medications listed on the AHCCCS Drug List when the List does not specify these requirements.

In addition, the Contractor is prohibited from denying coverage of a medically necessary medication when the member's primary insurer, other than Medicare Part D, refuses to approve the request and the primary insurer's grievance and appeals process has been completed. The Contractor shall evaluate the medical necessity of the submitted PA for all Federally and State reimbursable medications including those listed and those not listed on the AHCCCS Drug List.

The AHCCCS FFS PA criteria is posted on the AHCCCS website. AHCCCS Contractors shall follow and adhere to the AHCCCS FFS PA criteria effective October 1, 2022.

In addition, for medications that are Non-Preferred Drugs and not listed on the AHCCCS Drug List, the Contractor shall evaluate the submitted PA request on an individual basis.

5. Requests for Changes to the AHCCCS Drug List

   Requests for medication additions, deletions, or other changes to the AHCCCS Drug List shall be reviewed by the AHCCCS P&T Committee. Requests shall be submitted no later than 60 days prior to the AHCCCS P&T Meeting to the AHCCCS Pharmacy Department email at: AHCCCSPharmacyDept@azahcccs.gov

   The request shall include all the following information:
   a. Name of medication requested (brand name and generic name),
   b. Dosage forms, strengths and corresponding costs of the medication requested,
   c. Average daily dosage,
   d. The FDA indication and the accepted off–label use,
   e. Advantages or disadvantages of the medication over currently available products on the AHCCCS Drug List,
   f. Adverse Drug Event (ADE) reported with the medication,
   g. Specific monitoring requirements and costs associated with these requirements, and
   h. A clinical summary for the addition, deletion, or change request.

6. Quantity Limits/Step Therapy

   Step Therapy programs apply coverage rules at the point of service when a claim is adjudicated that typically require the use of a more cost-effective drug that is safe and effective to be used prior to approval of a more costly medication.

   For all Preferred Drugs specified on the AHCCCS Drug List, the Contractor shall adopt the quantity limits and Step Therapy requirements exactly as they are presented on the AHCCCS Drug List. For therapeutic classes not listed on the AHCCCS Drug List, the Contractor may develop Step Therapy requirements.

   The Contractor is not required to provide an NOA when the prescribing clinician is in agreement with the change to the first-line or preferred drug. A PA may be submitted for the second-line drug when the prescribing clinician is not in agreement with the transition request to the first-line drug. The Contractor shall issue an NOA in accordance with ACOM Policy 414 for Service Authorizations when a PA request is denied, or a previously approved authorization is terminated, suspended, or reduced.

B. GENERIC AND BIOSIMILAR DRUG SUBSTITUTIONS

1. The Contractor and FFS Programs shall utilize a mandatory Generic Drug substitution policy that requires the use of a generic equivalent drug whenever one is available. The exceptions to this requirement are:
   a. A brand name drug may be covered when a generic equivalent is available when the Contractor's negotiated rate for the brand name drug is equal to or less than the cost of the Generic Drug, and
   b. AHCCCS may require the Contractor to provide coverage of a brand name drug when the cost of the Generic Drug has an overall negative financial impact to the State. The overall financial impact to the State includes consideration of the Federal and supplemental rebates.

2. Prescribing clinicians shall clinically justify the use of a brand-name drug over the use of its generic equivalent through the PA process.

3. Generic and Biosimilar substitutions shall adhere to Arizona State Board of Pharmacy rules and regulations.

4. The Contractor 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.

C. ADDITIONAL INFORMATION FOR MEDICATION COVERAGE

1. Members transitioning to a different health plan or to FFS are covered for medications as follows:
   a. The transferring Contractor or AHCCCS shall provide coverage for medically necessary, cost-effective, and Federally and State reimbursable medications until such time that the member transitions to their new health plan or to the FFS Program, and
   b. The Contractor, FFS Program providers, and TRBHAs are responsible for coordinating care when transferring a member to a new health plan or to the FFS Program to ensure that the member's medications are continued during the transition.

2. The Contractor and FFS Programs shall provide coverage for medically necessary, cost-effective, and Federally and State reimbursable behavioral health medications provided by a Primary Care Provider (PCP) within their scope of practice. For the antipsychotic class of medications, PA may be required. This includes the monitoring and adjustments of behavioral health medications. For additional information refer to the AMPM Policy 510.

3. Behavioral Health Medication Coverage for AHCCCS members transitioning between a Behavioral Health Medical Professional (BHMP) and a PCP.

   For members transitioning from a BHMP to a PCP or from a PCP to a BHMP:
   PCPs and BHMPs shall coordinate the care and ensure that the member has a sufficient supply of medication(s) to last through the date of the member's first appointment with the PCP or BHMP.

4. Behavioral health medication coverage for members who are not enrolled in an integrated plan to obtain both physical and behavioral health services.

   For FFS program requirements regarding payment responsibility for physical and behavioral health services refer to FFS Billing Manual.

5. ACC-RBHA Drug Lists

   The ACC-RBHA Contractors, in aggregate, shall develop, and submit to AHCCCS for prior approval, the following Drug Lists for Non-Title XIX/XXI individuals, as specified in Contract:
   a. The Crisis Drug List,
   b. The SMI Drug List,
   c. The SED Drug List, and
   d. The SUBG Drug List.

   Additionally, for the Crisis Drug List, the initial prescription shall be written for up to a seven-day supply with one refill if applicable.

   The ACC-RBHAs shall post the Drug Lists on their respective websites.

6. Guest Dosing of Methadone or Buprenorphine
   An individual receiving Methadone or Buprenorphine administration services who is not a recipient of take-home medication may receive guest dosing of Methadone or Buprenorphine from the area Contractor when the individual is traveling outside of home Opioid Treatment Program (OTP) center.

7. Members Transitioning from Home OTP to another Receiving Opioid Treatment Program and Requiring Guest Dosing.

   Guest dosing is consistent with Substance Abuse and Mental Health Services Administration's (SAMHSA's) guidance regarding medication safety and recovery support. An individual may be administered sufficient daily dosing from an OTP center other than their Home OTP Center when they are unable to travel to the Home OTP Center or when traveling outside of the home OTP center's area, for business, pleasure, or emergency.

   The member may receive guest dosing from another OTP center (Guest OTP Center) within their Geographic Service Area (GSA), or outside their GSA. Guest dosing may also be approved outside the State of Arizona when the member's health would be endangered if travel were required back to the state of residence [42 CFR 431.52].
   a. A member may qualify for guest dosing when:
      i. The member is receiving administration of Medications for Opioid Use Disorder (MOUD) services from SAMHSA-Certified OTP,
      ii. The member needs to travel outside their Home OTP Center area,
      iii. The member is not eligible for take home medication, and
      iv. The Home OTP center (Sending OTP Center) and Guest OTP Center have agreed to transition the member to the Guest OTP center for a scheduled period of time.
   b. The Contractor shall have policies and processes in place for providers that include at a minimum the following:
      i. Title XIX/XXI members shall not be charged for guest dosing except as permitted by A.A.C. R9-22-702 *Charges to Members* and A.A.C. R9-22-711 *Copayments*,
      ii. Non-Title XIX/XXI eligible members shall not be charged copayments for guest dosing,
      iii. The **Sending OTP Center** shall:
         1) Forward information to the Receiving OTP Center prior to the member's arrival, Information shall include at a minimum:
            a) A valid release of information signed by the patient,

b) Current medications,
c) Date and amount of last dose administered or dispensed,
d) Physician order for guest dosing, including first and last dates of guest dosing,
e) Description of clinical stability including recent alcohol or illicit drug abuse,
f) Any other pertinent information,

2) Provide a copy of the information to the member in a sealed, signed envelope for the member to present to the Receiving OTP Center,
3) Submit notification to the Contractor of enrollment of the guest dosing arrangement, and
4) Accept the member upon return from the Receiving OTP Center unless other arrangements have been made.

iv. The Guest OTP Center shall:
1) Respond to the Sending OTP Center in a timely fashion, verifying receipt of information and acceptance of the member for guest medication as quickly as possible,
2) Provide the same dosage that the patient is receiving at the member's Sending OTP Center, and change only after consultation with Sending OTP Center,
3) Bill the member's Contractor of enrollment for reimbursement utilizing the appropriate coding and modifier,
4) Provide address of Guest OTP Center and dispensing hours,
5) Determine appropriateness for dosing prior to administering a dose to the member. The Guest OTP Center has the right to deny medication to a patient if they present inebriated or under the influence, acting in a bizarre manner, threatening violence, loitering, or inappropriately interacting with patients,
6) Communicate any concerns about a guest-dosing the member to the Sending OTP Center including termination of guest-dosing if indicated, and
7) Communicate last dose date and amount back to the Sending OTP Center.

D. OVER-THE-COUNTER MEDICATION

AHCCCS and its Contractors may cover an over-the-counter medication under the pharmacy benefit when it is prescribed in place of a covered prescription medication that is clinically appropriate, equally safe, and effective, and more cost effective than the covered prescription medication.

E. PRESCRIPTION DRUG COVERAGE, BILLING LIMITATIONS, AND PRESCRIPTION DELIVERY

1. A new prescription or refill prescription in excess of a 30-day supply is not covered unless:
   a. The medication is prescribed for chronic illness and the prescription is limited to no more than a 90-day supply,
   b. The member will be out of the provider's service area for an extended period of time and the prescription is limited to the extended time period, not to exceed 90 days, or
   c. The medication is prescribed for contraception and the prescription is limited to no more than a 90-day supply.

2. Prescription drugs for covered transplant services shall be provided in accordance with AMPM Policy 310-DD.

3. AHCCCS cover the following for members who are eligible to receive Medicare Part D:
   a. Over-the-counter medications that are not covered as part of the Medicare Part D prescription drug program and the drug meets the requirements in section D of this policy,
   b. A drug that is excluded from coverage under Medicare Part D by the Centers for Medicare and Medicaid Services (CMS) and the drug is medically necessary and Federally and State reimbursable, and
   c. Cost sharing for medications to treat behavioral health conditions for individuals with an SMI designation. Refer to AMPM Policy 320-T1 and AMPM Policy 320-T2.

4. Pharmacies shall not charge a member the cash price for a prescription, other than an applicable copayment, when the medication is Federally and State reimbursable and the prescription is ordered by an AHCCCS Registered Prescribing Clinician.

5. Pharmacies shall not split bill the cost of a prescription claim to AHCCCS or its Contractor's PBMs for an AHCCCS member. The Contractor's PBMs' Pharmacies shall not allow a member to pay cash for a partial prescription quantity for a Federally and State reimbursable medication when the ordered drug is written by an AHCCCS Registered Prescribing Clinician.

6. Pharmacies are prohibited from auto-filling prescription medications.

7. Pharmacies shall not submit prescriptions claims for reimbursement in excess of the Usual & Customary Price (U&C) charged to the general public.
   a. The sum of charges for both the product cost and dispensing fee may not exceed a pharmacy's U&C Price for the same prescription, and
   b. The U&C submitted ingredient cost shall be the lowest amount accepted from any member of the general public who participates in the pharmacy provider's savings or discount programs including programs that require the member to enroll or pay a fee to join the program.

8. Pharmacies that purchase drugs at a Nominal Price outside of 340B or the Federal Supply Schedule (FSS) shall bill their Actual Acquisition Cost of the drug.

9. Pharmacies, at their discretion, may deliver or mail prescription medications to an AHCCCS member or to an AHCCCS registered provider's office for a specific AHCCCS member.

F. PRIOR AUTHORIZATION (PA) REQUIREMENTS FOR LONG-ACTING OPIOID MEDICATIONS

1. Prior Authorization (PA) is required for all long-acting opioid prescription medications unless the member's diagnosis is one the following:
   a. Active oncology diagnosis with neoplasm related pain,
   b. Hospice care, or
   c. End of life care (other than hospice).

The prescriber shall obtain approval or an exception for all long-acting opioid prescription medications from the Contractor, Contractor's PBM or AHCCCS' PBM, as applicable.

G. 5 -DAY SUPPLY LIMIT OF PRESCRIPTION SHORT ACTING OPIOID MEDICATIONS

1. Members under 18 years of age
   a. Except as otherwise specified in Section G(1)(b), *Conditions and Care Exclusion from the 5-day Supply Limitation*, a prescriber shall limit the **initial and refill** prescriptions for any short-acting opioid medication for a member under 18 years of age to no more than a 5-day supply,
   An **initial** prescription for a short-acting opioid medication is one in which the member has not previously filled any prescription for a short-acting opioid medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the member's PBM prescription profile.
   b. Conditions and Care Exclusion from the 5-day Supply Limitation:
      i. The **initial and refill** prescription 5-day supply limitation for short-acting opioid medications *does not* apply to prescriptions for the following conditions and care instances:
         1) Active oncology diagnosis,
         2) Hospice care,
         3) End-of-life care (other than hospice),
         4) Palliative care,
         5) Children on an opioid wean at the time of hospital discharge,
         6) Skilled nursing facility care,
         7) Traumatic injury, excluding post-surgical procedures,
         8) Chronic conditions for which the provider has received PA approval through the Contractor, and
         9) Post-surgical procedures

         The **initial** prescription 5-day supply limitation for short-acting opioid medications does not apply to prescriptions for post-surgical procedures. However, initial prescriptions for short-acting opioid medications for post-surgical procedures are limited to a supply of no more than 14 days. Refill prescriptions for short-acting opioid medications for post-surgical procedures are limited to no more than a 5-day supply.

For additional information on the exclusions, refer to Attachment B.

For additional information on the traumatic injury ICD-10 codes, refer to Attachment C.

2. Members 18 years of age and older
   a. Except as otherwise specified in Section G(2)(b), *Conditions and Care Exclusion from the 5-day Supply Limitation*, a prescriber shall limit the **initial** prescription for any short-acting opioid medication for a member 18 years of age and older to no more than a 5-day supply.
   An **initial** prescription for a short-acting opioid medication is one in which the member has not previously filled any prescription for a short-acting opioid medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the member's PBM prescription profile, and
   b. Conditions and Care Exclusion from the 5-day Initial Supply Limitation. The **initial** prescription 5-day supply limitation for short-acting opioid medications *does not* apply to prescriptions for the following conditions and care instances:
      i. Active oncology diagnosis,

ii. Hospice care,
iii. Palliative care,
iv. Skilled nursing facility care,
v. Traumatic injury, excluding post-surgical procedures,
vi. Post-surgical procedures, and
vii. The medication is for SUD treatment.

Initial prescriptions for short-acting opioid medications for post-surgical procedures are limited to a supply of no more than 14 days.

For additional information on the exclusions, refer to Attachment B.

For additional information on the traumatic injury ICD-10 codes, refer to Attachment C.

H. ADDITIONAL FEDERAL OPIOID LEGISLATION (42 USC 1396A(OO)) MONITORING REQUIREMENTS

1. AHCCCS and its Contractors shall implement automated processes to monitor the following: Opioid safety edits at the Point-of-Sale including but not limited to the following:
   a. Days' supply limits for opioid naïve members,
   b. Quantity limits,
   c. Therapeutic duplication limitations, and
   d. Early fill limitations.

2. Opioid naïve members prescribed an opioid and the Morphine Equivalent Daily Dose (MEDD) is 50 or greater.

3. Member utilization when the cumulative current utilization of opioid(s) is a MEDD of greater than 90 and the member is not opioid naïve.

4. Members with concurrent use of an opioid(s) in conjunction with a benzodiazepine(s) and/or an antipsychotic(s).

5. Members are prescribed an opioid after being prescribed drugs used for MOUD or an OUD diagnosis.
6. Antipsychotic prescribing for children.

7. Fraud, Waste and Abuse by enrolled members, pharmacies, and prescribing clinicians.

8. Prospective and retrospective opioid reviews.

9. All Contractors shall report Drug Utilization Review (DUR) management activities annually as required by AHCCCS and the CMS.

10. Controlled substances as specified in A.R.S. § 32-3248.01:
    a. A health care professional may write for a prescription that is more than 90 Morphine Milligram Equivalents (MME) per day if the prescription is:
       i. A continuation of a prior prescription order issued within the previous 60 days,

ii. An opioid with a maximum approved total daily dose in the labeling as approved by the U.S. FDA,
iii. For a patient who has an active oncology diagnosis or a traumatic injury,
iv. Receiving opioid treatment for perioperative surgical pain,
v. For a patient who is hospitalized,
vi. For a patient who is receiving hospice care, end-of-life care, palliative care, skilled nursing facility care or treatment for burns,
vii. For a patient who is receiving MOUD for a substance use disorder, or
viii. For chronic intractable pain.

b. For additional information refer to the Arizona Opioid Epidemic Act.

I. NALOXONE

Naloxone is available as an over the counter or prescription medication that reverses the effects of an opioid overdose. AHCCCS and its Contractors cover and consider Naloxone an essential medication to reduce the risk and prevent an opioid overdose death. AHCCCS requires a prescriptive order for over the counter and prescription forms of naloxone, written by an AHCCCS registered provider, to be on file at the pharmacy when Naloxone is dispensed to or for a specific AHCCCS member.

1. A Standing Order written by the Medical Director of the Arizona Department of Health Services (ADHS) is on file at all Arizona pharmacies.
   a. When picking up Naloxone at a pharmacy, members may have to reference the standing order to the pharmacy staff. If the pharmacy staff is not aware of the standing order, ask one of the staff to send an email to AHCCCSPharmacyDept@azahcccs.gov.

2. Eligible candidates that may obtain Naloxone include but are not limited to:
   a. Members:
      i. Using illicit or non-prescription opioids with a history of such use,
      ii. With a history of opioid misuse, intoxication, and/or a recipient of emergency medical care for acute opioid poisoning,
      iii. Prescribed high dose opioid prescriptions of 90 MEDD or less if there are other risk factors,
      iv. Prescribed an opioid with a known or suspected concurrent alcohol use,
      v. From opioid detoxification and mandatory abstinence programs,
      vi. Treated with methadone for addiction or pain,
      vii. With an opioid addiction and smoking/Chronic obstructive pulmonary disease (COPD) or other respiratory illness or obstruction,
      viii. Prescribed opioids who also have renal, hepatic, cardiac or Human immunodeficiency virus (HIV)/ Acquired Immunodeficiency Syndrome (AIDs) disease,
      ix. Who may have difficulty accessing emergency services, and/or
      x. Assigned to a pharmacy and or prescribing clinician,
   b. Persons who request over the counter Naloxone and are the family member or friend of a member at risk of experiencing an opioid related overdose, and
   c. Persons who request over the counter Naloxone and are in the position to assist a member at risk of experiencing an opioid related overdose.

3. The Contractor and FFS Programs shall cover the following:
   a. Naloxone Solution plus syringes,
   b. Naloxone Nasal Spray known as Narcan Nasal Spray, including over the counter orders, and
   c. Refills of the above Naloxone products on an as needed basis.

4. Every recipient shall be educated on the use of Naloxone by the pharmacist dispensing the medication in accordance with Arizona State Board of Pharmacy Regulations.

5. Naloxone is contraindicated for members with a known history of hypersensitivity to Naloxone or any of its ingredients.

6. A copayment shall not be charged for Naloxone.

J. AHCCCS PHARMACY BENEFIT EXCLUSIONS

The following are excluded and are not covered:

1. Medications prescribed for the treatment of a sexual or erectile dysfunction, unless:
   a. The medication is prescribed to treat a condition other than a sexual or erectile dysfunction, and
   b. The FDA has approved the medication for the specific condition.

2. Medications that are personally dispensed by a physician, dentist, or other provider except in geographically remote areas where there is no participating pharmacy or when accessible pharmacies are closed.

3. Drugs classified as Drug Efficacy Study Implementation (DESI) drugs by the FDA.

4. Outpatient medications for members under the Federal Emergency Services Program, except for dialysis related medications for Extended Services individuals.

5. Medical Marijuana (refer to AMPM Policy 320-M).

6. Drugs eligible for coverage under Medicare Part D for AHCCCS members eligible for Medicare whether or not the member obtains Medicare Part D coverage with the exception of dual eligible members that have creditable coverage and/or individuals with an SMI designation:
   a. For creditable coverage Contractor requirements, refer to the ACOM Policy 201, and
   b. For Medicare Part D cost sharing Contractor requirements for medications to treat behavioral health conditions for persons with an SMI designation, refer to AMPM Policy 320-T1 and AMPM Policy 320-T2.

7. Medications determined to be experimental as specified in A.A.C. § 9-22-203, Experimental Services.

8. Medications furnished solely for cosmetic purposes.

9. Medications used for weight loss treatment.

K. RETURN OF AND CREDIT FOR UNUSED MEDICATIONS

AHCCCS and its Contractors shall require the return of unused medications to the outpatient pharmacy from nursing facilities upon the discontinuance of prescriptions due to the transfer, discharge, or death of a member. A payment/credit reversal shall be issued for unused prescription medications by the outpatient pharmacy to AHCCCS or the appropriate AHCCCS Contractor. The pharmacy may charge a reasonable restocking fee as agreed upon with AHCCCS and its Contractors. The return of unused prescription medication shall be in accordance with Federal and State laws. A.A.C. R4-23-409 allows for this type of return and the redistribution of medications under certain circumstances. Documentation shall be maintained and shall include the quantity of medication dispensed and utilized by the member.

A credit shall be issued to AHCCCS, if the member is enrolled in the AIHP, TRBHA, or FFS Program or to the member's Contractor for members who are not FFS when the unused medication is returned to the pharmacy for redistribution.

L. DISCARDED PHYSICIAN-ADMINISTERED MEDICATIONS

The discarded portion of Federally and State reimbursable physician administered drugs that are Unit-Dose or Unit-of-Use designated products in MediSpan or First DataBank shall be billed to AHCCCS and the Contractor. Providers shall use the most cost-effective product(s) for the required dose to be administered. For example, if the dose to be administered is 12mg and the product is available in a 10mg and 50mg vial, the provider shall use two- 10mg vials to obtain the 12mg dose.

The 12mg dose shall be billed as the administered dose and 8mg shall be billed as discarded waste using the JW modifier.

Effective 01/01/22, repackaged medications are not Federally and State reimbursable. AHCCCS and the Contractor shall not reimburse Unit-of-Use or Unit Dose repackaged drugs. The actual amount used and/or the discarded portion shall not be billed to AHCCCS or the Contractor for reimbursement.

For multidose products, providers shall only bill for the actual amount of drug that was used and AHCCCS and the Contractor shall only reimburse the actual amount of used drug.

M. PRIOR AUTHORIZATION (PA) CRITERIA FOR SMOKING CESSATION AIDS

AHCCCS has established PA criteria for tobacco cessation aids (refer to AMPM Exhibit 300-1).

N. VACCINES AND EMERGENCY MEDICATIONS ADMINISTERED BY PHARMACISTS TO INDIVIDUALS THREE YEARS OF AGE AND OLDER

AHCCCS covers vaccines and emergency medication without a prescription order when administered by a pharmacist who is currently licensed and certified by the Arizona State Board of Pharmacy consistent with the limitations of this Policy and as specified in A.R.S. § 32-1974.

For purposes of this section, "Emergency Medication" means emergency epinephrine and diphenhydramine. "Vaccines" are limited to AHCCCS covered vaccines as specified in the AMPM Policy 310-M.

Members Obtaining Immunizations at a Pharmacy:

1. Pharmacists, pharmacy interns, and technicians under the supervision of a pharmacist, within their scopes of practice, may only administer influenza and COVID immunizations to **children** who are three years through 18 years of age.

2. Pharmacists, and pharmacy interns and technicians under the supervision of a pharmacist, within their scopes of practice, may administer AHCCCS covered immunizations to adults 19 years of age and older as specified in A.R.S. § 32-1974.

3. The pharmacy providing the vaccine shall be an AHCCCS registered provider.

4. Contractors retain the discretion to determine the coverage of vaccine administration by pharmacists and pharmacy interns and technicians under the supervision of a pharmacist, coverage is limited to the Contractor's network pharmacies unless otherwise directed by AHCCCS.

O. 340B COVERED ENTITIES AND CLAIM SUBMISSION

A.R.S. § 36-2930.03 requires:

1. 340B covered entities shall submit the Actual Acquisition Cost of the drug for AHCCCS Members' point-of-sale prescriptions and physician-administered drug claims, that are identified on the 340B pricing file, whether or not the drugs are purchased under the 340B Drug Pricing Program.
   a. Point Of Sale (POS) claims shall be reimbursed at the lesser of:
      i. The Actual Acquisition Cost, or
      ii. The 340B Ceiling Price, and
      iii. A professional Fee (dispensing fee).
   b. Physician administered drugs shall be reimbursed at the lesser of the Actual Acquisition Cost or the 340B ceiling price, and the Professional (dispensing) Fee is not reimbursed and is not permitted when a physician administered drug is administered by the prescribing clinician.

2. AHCCCS and its Contractors shall not reimburse 340B Contracted Pharmacies for drugs that are purchased, dispensed, or administered as part of or subject to the 340B Drug Pricing Program.

3. The Contractor is required to comply with any changes to reimbursement methodology for 340B entities. Arizona 340B entity hospitals, and outpatient facilities owned and operated by a 340B entity hospital, are not exempt from the reimbursement methodology listed in Section P, 1 through 4 above. Effective with a future date to be determined, 340B hospitals and outpatient facilities, owned and operated by a 340B hospital, shall be required to submit claims at the entity's actual acquisition cost.

For additional details on claim submission and reimbursement refer to the CMS approved Outpatient Drug Rule State Plan Amendment.

A.A.C. R-9-22-710(C) describes the reimbursement methodology to be used by AHCCCS and its Contractors for Federally Qualified Health Center (FQHC) and FQHC Look-Alike Pharmacies for 340B drugs as well as reimbursement for Contract Pharmacies that have entered into a 340B drug purchasing arrangement with any 340B entity. The Rule also specifies reimbursement for FQHC and FQHC Look-Alike Pharmacies for drugs, which are not part of the 340B Drug Pricing Program. The rule is located on the A.A.C. R9-22-709.

P. PHARMACEUTICAL REBATES

The Contractor, including the Contractor's PBM, is prohibited from negotiating any rebates with drug manufacturers for preferred or other pharmaceutical products when AHCCCS has a supplemental rebate contract for the product(s). A listing of products covered under supplemental rebate agreements will be available on the AHCCCS website under the Pharmacy Information section. If the Contractor or its PBM has an existing rebate agreement with a manufacturer, all outpatient drug claims, including provider-administered drugs for which AHCCCS is obtaining supplemental rebates, shall be exempt from such rebate agreements.

Q. INFORMED CONSENT

Informed consent shall be obtained from the member, or as applicable, the member's Health Care Decision Maker (HCDM) for each psychotropic medication prescribed. The comprehensive clinical record shall include documentation of the essential elements for obtaining informed consent. Essential elements for obtaining informed consent for medication are contained within Attachment A. The use of Attachment A is recommended as a tool to document informed consent for psychotropic medications. Additional information is contained in AMPM Policy 320-Q.

R. YOUTH ASSENT

Youth and Psychotropic Medications

Youth under the age of 18 are to be educated on options, allowed to provide input, and encouraged to assent to medication(s) being prescribed. Information is discussed with the youth in a clear and age-appropriate manner consistent with the developmental needs of the youth.

The information to be shared with a minor patient shall be consistent with the information shared in obtaining informed consent from adults. Informed consent for a minor shall be obtained through the minor's authorized HCDM unless the minor is emancipated.

Discussion of the youth's ability to give consent for medications at the age of 18 years old is begun no later than age 17½ years old, especially for youth who are not in the custody of their parents.

Special attention shall be given to the effect of medications on the reproductive status and pregnancy, as well as long term effects on weight, abnormal involuntary movements, and other health parameters.

Evidence of the youth's consent to continue medications after their 18th birthday may be documented through use of Attachment A.

S. COMPLEMENTARY AND ALTERNATIVE MEDICINE

Complementary and Alternative Medicines are not AHCCCS reimbursable.

T. PRESCRIPTION DRUG COUNSELING

AHCCCS requires pharmacists, and graduate and non-graduate pharmacy interns, under the supervision of a pharmacist, to provide counseling on prescription drugs, prescribed and dispensed to AHCCCS members, in accordance with the Arizona State Board of Pharmacy A.A.C. 4-23-402.