



310-V PRESCRIPTION MEDICATIONS/PHARMACY SERVICES

REVISION DATES: 07/01/16, 01/01/16, 02/01/15, 08/01/14, 03/01/14, 01/01/13, 10/01/12,
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10/01/01, 10/01/97, 10/01/96

INITIAL
EFFECTIVE DATE: 10/01/1994

DEFINITIONS

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 preferred drugs used by 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 was developed to encourage the use of safe, effective, clinically appropriate, and the most cost-effective medications.

AHCCCS BEHAVIORAL HEALTH DRUG LIST A list of preferred behavioral health medications that are to be used by all Contractors responsible for the administration of behavioral health pharmacy benefits, including but not limited to Long Term Care, Children's Rehabilitative Services, and RBHAs, which are. This drug list is limited to federally and state reimbursable behavioral health medications that are supported by current evidence-based medicine. The AHCCCS Behavioral Health Drug List was developed to encourage the use of safe, effective, clinically appropriate, and the most cost-effective behavioral health medications.

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.



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.
MEDICATION ERROR	The inappropriate use of a drug that may or may not result in harm; such errors may occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring of a drug.
NON-PREFERRED DRUG	A medication that is not listed on the AHCCCS Drug List or the AHCCCS Behavioral Health Drug List. Non-Preferred drugs require prior authorization.
PHARMACY AND THERAPEUTICS (P&T) COMMITTEE	The advisory committee to the AHCCCS Administration, which is responsible for developing, managing, updating, and administering the AHCCCS Drug List and AHCCCS Behavioral Health Drug List. The P&T Committee is primarily comprised of physicians, pharmacists, nurses, and other health care professionals.
PREFERRED DRUG	A medication that has been clinically reviewed and approved by the AHCCCS P&T Committee for inclusion on the AHCCCS Drug List and/or the AHCCCS Behavioral Health Drug List as a preferred drug due to its proven clinical efficacy and cost effectiveness.
SERIOUS MENTAL ILLNESS (SMI)	A diagnosis of, a condition defined in A.R.S. §36-550 and diagnosed in a person 18 years of age or older.
STEP THERAPY	The practice of initiating drug therapy for a medical condition with the most cost-effective and safest drug, and stepping up through a sequence of alternative drug therapies as a preceding treatment option fails.

DESCRIPTION

Medically necessary, cost-effective, and federally and state reimbursable medications prescribed by a physician, physician's assistant, nurse practitioner, dentist, or other AHCCCS registered practitioner and dispensed by an AHCCCS registered licensed pharmacy are covered for members consistent with 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 who have a diagnosis of Serious Mental Illness, pursuant to A.R.S. §36-550.



AMOUNT, DURATION AND SCOPE

A. THE AHCCCS DRUG LIST AND THE AHCCCS BEHAVIORAL HEALTH DRUG LIST

The AHCCCS Pharmacy and Therapeutics (P&T) Committee is responsible for developing, managing, and updating the AHCCCS Drug List and the AHCCCS Behavioral Health Drug List to assist providers in selecting clinically appropriate and cost-effective drugs for AHCCCS members. The AHCCCS P&T Operational Policy can be located at: <http://www.azahcccs.gov/commercial/pharmacyupdates.aspx>

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 must include all drugs listed on the AHCCCS Drug List and/or the AHCCCS Behavioral Health Drug List, as appropriate, as further detailed below.

The AHCCCS Drug List and the AHCCCS Behavioral Drug List are not all-inclusive lists of medications for AHCCCS members. Contractors 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 these lists.

1. Preferred Drugs

The AHCCCS Drug List and the AHCCCS Behavioral Health Drug List designate medications that are preferred drugs for specific therapeutic classes. Contractors are required to maintain preferred drug lists which include each and every drug exactly as listed on the AHCCCS Drug List and/or the AHCCCS Behavioral Health Drug List, as applicable. When the AHCCCS Drug List and/or AHCCCS Behavioral Health Drug List specify a preferred drug(s) in a particular therapeutic class, Contractors are not permitted to add other preferred drugs to their preferred drug lists in those therapeutic classes.

Contractors 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 will become effective on the first day of the first month of the quarter following the P&T Meeting unless otherwise communicated by AHCCCS.

Contractors shall approve the preferred drugs listed for the therapeutic classes contained on the AHCCCS Drug List and/or the AHCCCS Behavioral Health Drug List, as appropriate, before approving a nonpreferred drug unless:



- a. The member has previously completed step therapy using the preferred drug(s), or
- b. The member's prescribing clinician supports the medical necessity of the non-preferred drug over the preferred drug for the particular member.

Contractors are not required to provide a Notice of Action when the prescribing clinician is in agreement with the change to the preferred drug. A prior authorization request may be submitted for the non-preferred drug when the prescribing clinician is not in agreement with transition to the preferred drug. Contractors shall issue a Notice of Action in accordance with AHCCCS Contractor Operations Manual (ACOM) Policy 414 for Service Authorizations when a prior authorization request is denied or a previously approved authorization is terminated, suspended, or reduced.

2. 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 and/or the AHCCCS Behavioral Health 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 Contractors the non-preferred drugs that have been approved for grandfathering; Contractors are required to grandfather members on these medications.

3. Prior Authorization

- a. The AHCCCS Behavioral Health Drug List

The AHCCCS Behavioral Health Drug List specifies which medications require Prior-Authorization (PA). Contractors must apply the same PA criteria as those specified on the AHCCCS website for medications listed on the AHCCCS Behavioral Health Drug List that require prior authorization prior to dispensing the medication. When a medication on the AHCCCS Behavioral Health Drug List is subject to PA but no PA criteria is specified, the Contractor may elect to establish PA criteria based on clinical appropriateness, scientific evidence, and standards of practice that include, but are not limited, to all of the following:

- i. Food and Drug Administration (FDA) approved indications and limits,
- ii. Published practice guidelines and treatment protocols,



- iii. 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,
- iv. Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies, and
- v. Drug reference resources (e.g. Micromedex, Drug Facts and Comparisons, UpToDate)

Contractors are prohibited from adding prior authorization and/or step therapy requirements to medications listed on the AHCCCS Behavioral Health Drug List when the list does not specify these requirements.

In addition, for those behavioral health medications that are non-preferred drugs and not listed on the AHCCCS Behavioral Health Drug List, Contractors shall evaluate the submitted prior authorization request on an individual basis.

All federally and state reimbursable drugs that are not listed on the AHCCCS Behavioral Health Drug List or Contractors' drug lists must be available through the prior authorization process.

b. The AHCCCS Drug List

Contractors administering the pharmacy benefit using the AHCCCS Drug List are responsible for establishing prior authorization criteria for medications which require prior authorization as identified on the AHCCCS Drug List with the exception of Smoking Cessation medications and Direct Acting Antiviral Hepatitis C medications. The AHCCCS Administration has developed criteria applicable to all Contractors for Smoking Cessation medications and for Direct Acting Antiviral Hepatitis C medications.

For all other medications subject to PA, Contractors may elect to establish PA criteria based on clinical appropriateness, scientific evidence and standards of practice that include, but are not limited, to all of the following:

- i. FDA approved indications and limits,
- ii. Published practice guidelines and treatment protocols,
- iii. 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,
- iv. Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies, and



- v. Drug reference resources (e.g. Micromedex, Drug Facts and Comparisons, UpToDate).

In addition, for medications that are non-preferred drugs and not listed on the AHCCCS Drug List, Contractors shall evaluate the submitted prior authorization request on an individual basis.

Contractors shall not add prior authorization and/or step therapy requirements to medications listed on the AHCCCS Drug List when the list does not identify the medication as being subject to prior authorization or step therapy.

All federally and state reimbursable drugs that are not listed on the AHCCCS Drug List or Contractors' drug lists must be available through the prior authorization process.

A medication shall not be denied solely due to the lack of a FDA indication. Off-label prescribing may be clinically appropriate as outlined above in 3.b.(ii.) through (v.).

The RBHA Contractors and the AHCCCS Administration shall cover medically necessary federally and state reimbursable behavioral health medications for persons who are Title XIX, Title XXI, and for persons who are SMI, regardless of whether or not they are eligible for Title XIX or Title XXI. It is not a basis to deny coverage of a medically necessary medication when the member's insurer, other than Medicare Part D, refuses to approve the request or appeal for a medication listed on the AHCCCS Behavioral Drug List.

4. Requests for Changes to the AHCCCS Drug List/AHCCCS Behavioral Health Drug List

Requests for medication additions, deletions or other changes to the AHCCCS Drug List and/or the AHCCCS Behavioral Health Drug List shall be reviewed by the AHCCCS P&T Committee. Requests must 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 must include all of 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. FDA indication and accepted off – label use,
- e. Advantages or disadvantages of the medication over currently available products on the AHCCCS Drug List,
- f. Adverse Drug Events reported with the medication,
- g. Specific monitoring requirements and costs associated with these requirements, and
- h. A detailed clinical summary.

5. Quantity Limits / Step Therapy

For all preferred drugs on the AHCCCS Drug List and the AHCCCS Behavioral Health Drug List, the Contractor must adopt the quantity limits and step therapy requirements exactly as presented in the AHCCCS Drug List and the AHCCCS Behavioral Health Drug List.

Step Therapy programs apply coverage rules at the point of service when a claim is adjudicated. If a claim is submitted for a second-line drug, which is a medication that is not the first drug normally used to treat a condition, the claim will reject. A message is transmitted to the pharmacy stating that the first-line drug treatment must be tried before coverage of the second-line drug can be authorized unless there is a clinical justification for not using the first line drug.

Contractors are not required to provide a Notice of Action when the prescribing clinician is in agreement with the change to the first-line drug. A prior authorization 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. Contractors shall issue a Notice of Action in accordance with ACOM Policy 414 for Service Authorizations when a prior authorization request is denied, or a previously approved authorization is terminated, suspended or reduced.

B. GENERIC AND BIOSIMILAR DRUG SUBSTITUTIONS

1. Contractors must 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.
 - b. AHCCCS may require Contractors 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 must clinically justify the use of a brand-name drug over the use of its generic equivalent through the prior authorization process.
3. Generic and biosimilar substitutions shall adhere to Arizona State Board of Pharmacy rules and regulations.
4. AHCCCS 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.

C. BEHAVIORAL HEALTH MEDICATION COVERAGE

The AHCCCS Pharmacy and Therapeutics Committee advises AHCCCS on the management of the AHCCCS Behavioral Health Drug List.

1. Behavioral Health Medication Coverage for Fee-For-Service and Acute Care members transitioning to a TRBHA or a RBHA

The AHCCCS Administration and its Contractors shall provide coverage for medically necessary, cost-effective, and federally and state reimbursable behavioral health medications until such time that the member transitions to a RBHA Contractor. The AHCCCS Contractors, the TRBHAs and RBHAs are responsible for coordinating care to ensure that the member's behavioral health medications are continued during this transition.

2. Behavioral Health Medications Prescribed by the Primary Care Provider (PCP) for the Treatment of Anxiety, Depression and Attention Deficit Hyperactivity Disorder (ADHD)

The AHCCCS Administration and its Contractors shall provide coverage for medically necessary, cost-effective, and federally and state reimbursable behavioral health medications prescribed by a PCP when used to treat depression (including postpartum depression), anxiety and ADHD; this includes the monitoring and adjustments of behavioral health medications.

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

Members transitioning from a BHMP to a PCP for their behavioral health medication management shall be continued on the medication(s) prescribed by the BHMP until they transition to their PCP. The AHCCCS Contractors and RBHA Contractor must coordinate the care and ensure that the member has a sufficient supply of behavioral health medications to last through the date of the member's first appointment with their PCP. Members receiving behavioral



health medications from their PCP may simultaneously receive counseling and other medically necessary services from the TRBHA or RBHA.

4. Behavioral Health Medication Coverage for Members Enrolled in the Comprehensive Medical and Dental Program (CMDP), Children's Rehabilitative Services (CRS) and Arizona Long Term Care System (ALTCS) Programs

CMDP and the Division of Developmental Disabilities (DDD) members who are not receiving any CRS services shall receive behavioral health services and medications through the RBHAs or the AHCCCS Administration. CMDP and DDD members receiving CRS services shall receive behavioral health services and medications through the AHCCCS CRS Contractor. ALTCS E/PD members shall receive behavioral health services and medications through their ALTCS E/PD Contractor.

5. Courtesy Dosing of Methadone

A person receiving methadone administration services who is not a recipient of take home medication may receive up to two courtesy doses of methadone from a RBHA when the person is traveling outside of their home RBHA area. All incidents of the provision of courtesy dosing must be reported to the person's home RBHA. The home RBHA must reimburse the other RBHA providing the courtesy doses upon receipt of properly submitted bills or encounters.

D. OVER-THE-COUNTER MEDICATION

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 LIMITATIONS

1. A new prescription or refill prescription in excess of a 30-day supply or a 100-unit dose is not covered unless:
 - a. The medication is prescribed for chronic illness and the prescription is limited to no more than a 100-day supply or 100-unit dose, whichever is greater,
 - 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 100 days or 100-unit dose, whichever is greater, or



- c. The medication is prescribed for contraception and the prescription is limited to no more than a 100-day supply.
2. Prescription drugs for covered transplantation services will be provided in accordance with AHCCCS transplantation policies.
3. AHCCCS covers the following for persons diagnosed with SMI and AHCCCS members who are eligible to receive Medicare:
 - a. Over-the-counter medications that are not covered as part of the Medicare Part D prescription drug program and which meet the requirements in section D of this policy.
 - b. A drug that is excluded from coverage under Medicare Part D by CMS and the drug is medically necessary and federally reimbursable.

F. AHCCCS PHARMACY BENEFIT EXCLUSIONS

The following are excluded from the pharmacy benefit:

1. Medication prescribed for the treatment of a sexual or erectile dysfunction, unless:
 - i. The medication is prescribed to treat a condition other than a sexual or erectile dysfunction, and
 - ii. The Food and Drug Administration 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 Food and Drug Administration.
4. Outpatient medications for members under the Federal Emergency Services Program.
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.
7. Pharmacies are prohibited from auto-filling prescription medications.



8. Experimental medications are excluded from coverage.

G. 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 (NFs) 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 the AHCCCS Administration or the appropriate AHCCCS Contractor. The pharmacy may charge a reasonable restocking fee as agreed upon with the AHCCCS Administration 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 must be maintained and must include the quantity of medication dispensed and utilized by the member. A credit must be issued to the AHCCCS Administration, if the member is enrolled in the American Indian Health Plan/TRBHA/Fee-For-Service (AIHP/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.

H. PRIOR AUTHORIZATION CRITERIA FOR SMOKING CESSATION AIDS

AHCCCS has established prior authorization criteria for smoking cessation aids (refer to AMPM Policy 320-K-1).

I. PRIOR AUTHORIZATION CRITERIA FOR DIRECT ACTING ANTIVIRAL TREATMENT FOR HEPATITIS C

AHCCCS has established prior authorization criteria for the use of medications for the treatment of Hepatitis C (refer to AMPM Policy 320-N).

J. VACCINES AND EMERGENCY MEDICATIONS ADMINISTERED BY PHARMACISTS TO PERSONS AGE 18 YEARS 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 state law A.R.S. §32-1974.

1. For purposes of this section "Emergency Medication" means emergency epinephrine and diphenhydramine. "Vaccines" are limited to pneumococcal and influenza vaccines.



2. The pharmacy providing the vaccine must be an AHCCCS registered provider (see note below regarding Indian Health Services (IHS)/638 outpatient facilities).
3. Contractors retain the discretion to determine the coverage of vaccine administration by pharmacists and coverage is limited to the Contractor's network pharmacies.

NOTE: IHS and 638 facilities may bill the outpatient all-inclusive rate for pharmacist vaccine administration as noted in section J of this policy.

K. 340B REIMBURSEMENT

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. This rule is located on the AHCCCS Website:

http://www.azahcccs.gov/reporting/Downloads/UnpublishedRules/NOER_340B_FQHC_010512.pdf

L. 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, must be exempt from such rebate agreements.

M. INFORMED CONSENT

Informed consent must be obtained from the member and/or legal guardian for each psychotropic medication prescribed. The comprehensive clinical record must include documentation of the essential elements for obtaining informed consent. Essential elements for obtaining informed consent for medication are contained within AMPM Policy 310-V, Exhibit 310-V-1. The use of AMPM Policy 310-V, Exhibit 310-V-1 is recommended as a tool to document informed consent for psychotropic medications. Additional information is contained in AMPM Policy 320-Q.



REFERENCES

- Acute Care Contract, Section D,
- ALTCS/EPD Contract, Section D,
- CRS Contract, Section D,
- DCS/CMDP Contract, Section D,
- DES/DDD Contract, Section D,
- RBHA Contract, Scope of Work
- AMPM Policy 320-K-1
- AMPM Policy 320-M
- AMPM Policy 320-N
- AMPM Policy 320-Q
- Exhibit 310-V-1, Informed Consent-Assent for Psychotropic Medication Treatment
- ACOM Policy 414
- AHCCCS Behavioral Health Drug List
- AHCCCS Pharmacy and Therapeutics (P&T) Operational Policy
<http://www.azahcccs.gov/commercial/pharmacyupdates.aspx>
- AHCCCSPharmacyDept@azahcccs.gov
- American Indian Health Plan/TRBHA/Fee-For-Service (AIHP/FFS) Program
- Indian Health Services (IHS)/638
- Centers for Medicare and Medicaid Services (CMS) State Medicaid Director Letter dated March 22, 2006
- U.S. Food and Drug Administration (FDA)
- 9 A.A.C. 22 Article 2
- 9 A.A.C. 28 Article 2
- 9 A.A.C. 31 Article 2
- A.A.C. R4-23-409
- A.A.C. R-9-22-710 (C)
- A.R.S. §36-550
- A.R.S. §32-1974