Clinical Policy: Non-Preferred Drugs and Brand Name Override

Reference Number: AZ.CP.PMN.16
Effective Date: 04.19
Last Review Date: 10.19
Line of Business: Arizona Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that Arizona Complete Health facilitates utilization of the preferred drugs listed for the therapeutic classes contained on the Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug List (PDL) as appropriate. This policy should only be used when there is no AZCH drug specific coverage criteria for the requested drug that is not listed on the AHCCCS PDL.
The AHCCCS PDL can be accessed on the AHCCCS website: https://www.azahcccs.gov/

Brand name drugs require review prior to approval. A generic drug is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic substitution with A-rated generic equivalents is mandatory for AHCCCS health plans unless brand name drugs are on AHCCCS Preferred Drug List. Brand name drugs may be approved in certain circumstances where there are adverse reactions to or therapeutic failure of generic drugs.

FDA Approved Indication(s)

Varies by drug product.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health that Non-Preferred drugs or brand name drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for a Non-Preferred Drug or Brand Name (must meet all)**:**

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);
   ** Requests for off-label use should also be reviewed against AZ.CP.PMN.53 – Off-Label Use Policy*
2. If request is for combination product, or alternative dosage form, or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);
   **Use of samples or of a copay card or discount card does not constitute medical necessity and is not allowed by plan*
3. Failure of at least two PDL agents as described below (a and b) at the maximum indicated dose, each used for the appropriate duration of treatment or for ≥ 30 days

for diseases requiring maintenance treatment, unless documented contraindications or clinically significant adverse effects are included with request:
   a. Alternative agents are within the same therapeutic class as the prescribed agent;
   b. If there is 1 or no PDL agent within the same drug class, member must use at least 2 PDL agents that are recognized as standard of care for the treatment of the relevant diagnosis, provided that such agent exists;
4. Trial and failure of PDL agents are supported by presence of paid claims in pharmacy claims history and documentation showing the failure of the two PDL agents;
5. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
6. If request is for brand name drug in lieu of generic formulation (must meet all):
   a. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);
   b. Failure of an adequate trial of or clinically significant adverse effects to two generics* of the requested brand name drug, each from a different manufacturer, unless member has contraindications to the excipients in all generics;
   **If a second generic of the requested brand name drug is not available, member must try a preferred generic drug from a similar therapeutic class (e.g., meloxicam for Naprosyn) that is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex) for the requested indication, provided that such agent exists*
   c. If clinically significant adverse effects were experienced, provider submits a copy of the MedWatch form(s) submitted to the FDA (see Appendix D);
   d. Provider submits clinical rationale* supporting why the brand name drug will be more effective than the generic or will not produce the same adverse effects as the generic;
   **Use of a copay card or discount card does not constitute medical necessity*
   e. Request meets one of the following (i or ii):
      i. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
      ii. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: Duration of request or 6 months (whichever is less)

II. Continued Therapy

A. Request for a Non-Preferred Drug or Brand Name (must meet all):

1. One of the following (a or b):
   a. Currently receiving medication via Centene benefit;
   b. Member has previously met initial approval criteria*;
   **If request is for a Non-Preferred Drug which was taken off of the PDL, has no AZCH specific criteria, and grandparenting is not allowed, refer to initial approval criteria;*
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
PDL: preferred drug list

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

- The AHCCCS Preferred Drug List designates medications that are preferred drugs for specific therapeutic classes. All AHCCCS Plans are required to maintain preferred drug lists that include each and every drug exactly as listed on the AHCCCS Preferred Drug List, as applicable. When the AHCCCS Preferred Drug List specifies a preferred drug(s) in a particular therapeutic class, all AHCCCS Plans are not permitted to add other preferred drugs to their preferred drug lists in those therapeutic classes.
- For biosimilars, AHCCCS health plans shall not transition to a biosimilar drug until AHCCCS has determined that the biosimilar drug is more cost-effective to the state than the continued use of the brand name drug.

V. Dosage and Administration
Varies by drug product.

VI. Product Availability
Varies by drug product

VII. References
Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created.	03.30.19	04.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed the policy number and name to AZ.CP.PMN.16. Non-Preferred drugs and Brand Name override. Edited Description section to clarify the intent of this policy: use of AHCCCS PDL agents, and brand name override whenever appropriate Added Appendix D: General Information: Contractor memo from 5/15/2019	07.25.19	
Added requirement for failure of at least two generics from two different manufacturers, MedWatch report, and clinical rationale from the provider for brand name override. Clarified PDL removal situations.	10.3.19	10.19
1Q 2020 annual review: revised to limit indications to FDA-approved uses and added reference to off-label use policy; removed 'for the relevant off-label use' from dosing limits; references reviewed and updated.	01.14.20	01.2020

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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