Clinical Policy: SABG Drug List Exception Requests

Reference Number: AZ.CP.PMN.1009
Effective Date: 10.01.19
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Line of Business: Arizona Medicaid (AzCH-CCP) 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 members follow selection elements established by AzCH-CCP for drugs used for Substance Use Disorder (SUD) treatment when not on the Substance Abuse Block Grant (SABG) preferred drug list (PDL).

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-Complete Care Plan that SABG Drug List Exception Requests are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Prescribed indication meets one of the following (a or b).
   a. Requested indication is for a Substance Use Disorder (e.g. including alcohol, opioid, benzodiazepine, stimulant or other drug use disorder)
   b. Request is for the supportive treatment of withdrawal symptoms for a Substance Use Disorder
2. Prescribed indication is FDA-approved or supported by standard pharmacopeias or treatment guidelines (*see Appendix D*);
3. One of the following:
   a. If there are at least three preferred alternatives, history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to at least THREE preferred alternatives (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request);
   b. If there are fewer than three preferred alternatives, the patient must have a history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the preferred products (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request);

4. There are no preferred formulary alternatives for the requested drug; If request is for a brand name drug, ONE of the following (a or b):
   a. BOTH of the following (i and ii):
      i. The brand is being requested because of an adverse reaction, allergy or sensitivity to the generic and the prescriber must attest to submitting the FDA MedWatch Form for allergic reactions to the medications;
      ii. If there are generic product(s), the member has tried at least three (if available);
   b. ONE of the following (i, ii, or iii):
      i. The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure);
      ii. The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided);
      iii. Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the member (rationale must be provided);
5. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   b. 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 3 months (whichever is less)

B. Other diagnoses/indications

No diagnoses other than Substance Use Disorder or supportive treatment for withdrawal symptoms are a covered benefit.

II. Continued Therapy

A. Request for a Brand Name or Non-PDL Drug (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;
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: 6 months

III. Diagnoses/Indications for which coverage is NOT authorized: No diagnoses other than Substance Use Disorder or supportive treatment for withdrawal symptoms are a covered benefit.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list
SABG: Substance Abuse Block Grant

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

1. The SABG is used to assist those who are uninsured or underinsured in the following populations (as funding is available AND in order of priority):
   a. Pregnant women/teenagers who use drugs by injection;
   b. Pregnant women/teenagers who use substances;
   c. Other members who use drugs by injection;
   d. Substance using women/teenagers with dependent children and their families, including women who are attempting to regain custody of their children; and
   e. As Funding is Available - all other members with a SUD, regardless of gender or route of use.
2. Members must indicate active substance use within the previous 12-months to be eligible for SABG services. This also includes individuals who were incarcerated and reported using while incarcerated. The 12-month standard may be waived for members on medically necessary methadone maintenance upon assessment for continued necessity as well as members incarcerated for longer than 12 months that indicate substance use in the 12 months prior to incarceration.
3. Covered medications are listed in the Arizona Medicaid Benefit Master Grid- Substance Abuse Coverable Drug tab. https://cnet.centene.com/sites/HNC-EPSC/Shared%20Documents/Forms/main%20view.aspx?RootFolder=%2Fsites%2FHNC%2DEPSC%2FShared%20Documents%2FFormulary%20and%20Benefits%20Management%2FReference%20Tools%2FBenefit%20Master%20Grids%20Centene%20%28ESI%20Platform%20ONLY%29%2FMedicaid&FolderCTID=0x012000 69AB859F17447747A07FA4CC60DBDE5C&View=%7B3758A40A%2DA2F6%2D4802%2D9883%2DD3D229C36DC5%7D
4. List of appropriate compendia of current literature:
   a. 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
k. Other drug reference resources

V. Dosage and Administration

Varies by drug product.

VI. Product Availability

Varies by drug product

VII. References

1. AHCCCS Medical Policy Manual (AMPM) 320-T Non-Discretionary Federal Grants.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Created Policy	09.19	10.19
2020 Annual review; minor formatting changes	09.20	10.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21
Annual Review; no updates.	2.15.22	03.22
Annual Review; updated criteria on preferred alternatives trial and failure and brand name drug request to mirror AHCCCS Fee-For-Service Prior Authorization Criteria for Non-Preferred Drugs; added a list of appropriate compendia of current literature in Appendix D.	02.10.23	02.23
1Q 2024 annual review: no updates	1.31.24	
1Q 2025 annual review; Removed reference to Care1st Health plan and logos.	02.10.25	

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.

herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.