Clinical Policy: SABG Drug List Exception Requests

Reference Number: AZ.CP.PMN.1009
Effective Date: 10.01.19
Last Review Date: 09.19
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) 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 patients follow selection elements established by AzCH for drugs used for Substance Use Disorder treatment when not on the Substance Abuse Block Grant (SABG- CVS Plan Code 9180SAB) 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 and Care1st 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. Drug is FDA-approved or supported by standard pharmacopeias or treatment guidelines (e.g DrugDex)
3. 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*
4. Failure of at least two PDL alternatives at the maximum indicated dose unless documented contraindications or clinically significant adverse effects are included with request (must meet all):
    a. Alternative drugs are within the same therapeutic class that are FDA-approved for the same indication
    b. Each alternative drug is used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment;

c. If there are < 2 PDL alternative drugs within the same drug class, member must use at least 2 PDL drugs that are recognized as standard of care for the treatment of the relevant diagnosis provided that such agent exists.
d. There are documented paid claims for member;

4. 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*).
5. Request 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., alcohol withdrawal seizure requests for brand Tegretol will require valproic acid trial in addition to carbamazepine trial/contraindication) 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;
   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 or samples does not constitute medical necessity*

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 Substance Abuse Prevention and Treatment Block Grant (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 Complete Health- Complete Care Plan 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%20Manage

ment%2FReference%20Tools%2FBenefit%20Master%20Grids%20Centene%20%28CVS%20Platform%20ONLY%29%2FMedicaid&FolderCTID=0x01200069AB859F17447747A07FA4CC60DBDE5C&View=%7B3758A40A%2DA2F6%2D4802%2D9883%2DD3D229C36DC5%7D

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

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed 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.