BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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COMPOUND MEDICATION – NON-FORMULARY (QUALIFIED HEALTH PLANS)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

COMPOUND MEDICATION – NON-FORMULARY (QUALIFIED HEALTH PLANS)

Criteria:

- **Criteria for initial therapy:** Compound medication is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Medical necessity or justification for use must be submitted with the request by prescriber office

  2. Use of the requested compound must
     a. Follow plan specific benefit design
     b. Not be used for cosmetic purpose
     c. Not be considered manufacturing and/or distribution

  3. Individual has failure, contraindication or intolerance to a commercially available alternative product used in the same route as the requested compound for the given diagnosis and proposed duration of therapy

  4. For ingredient(s) that normally require precertification, all criteria for precertification of the ingredient(s) are met

  5. The compound medication must contain at least one FDA-approved federal legend drug

  6. The active ingredient(s) in the compound medication is/are FDA-approved or supported by national compendia or peer-reviewed scientific literature for the for **ALL** of the following:
     a. Diagnosis
     b. Route of delivery
     c. Therapeutic amounts
     d. Safety and effectiveness
     e. Proposed duration of therapy

  7. The compound prescription meets **ONE** of the following:
     a. Requested compound is not already commercially available in the dosage form, route of administration, or dose requested from any pharmaceutical manufacturer
     b. Contains an ingredient(s) that is/are in short supply
     c. Compound needs to be prepared without some of the inactive ingredients (such as dyes, preservatives, sugars, flavoring, etc.) that are found in the commercially available product
     d. Individual requires a unique dosage form or concentration because individual is unable to take a solid dosage form or dose based on age or weight

  8. The compound must not contain **ANY** of the following:
     a. Ingredient(s) used for non-FDA approved use for the diagnosis being treated
     b. Ingredient(s) that are investigational or experimental
     c. Ingredient(s) not FDA approved for compounding
     d. Ingredient(s) that has been removed from the market due to safety or effectiveness concerns
     e. Ingredient(s) compound for the purpose of convenience only

  Initial approval duration: 6 months

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- **Criteria for continuation of coverage (renewal request):** Compound medication is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. The individual has benefited from therapy and remains at high risk and as such requires continued therapy
  2. The condition has not progressed or worsened while on therapy
  3. The request is for the same compound as originally approved (same dose form, strength, ingredients, etc.)
  4. Individual has been adherent with the medication
  5. Individual has not developed any contraindications or other exclusions to its continued use

  Renewal duration: 12 months

Description:

Compound medications are medications that contain at least one FDA-approved prescription component and are custom-mixed by a pharmacist or other healthcare professional to create a medication tailored to an individual patient's need. It must contain at least one federal legend drug in therapeutic amounts. A federal legend drug is defined as a medication product whereby federal law prohibits dispensing without a prescription. The compound medication must not be already commercially available in the dosage form, route of administration, or dose from any pharmaceutical manufacturer. Bulk chemicals, medical food supplements and nutritional additives not approved for dispensing by prescription are not considered federal legend drugs.

Compound medications are considered Non-Formulary for BCBSAZ members with a Qualified Health Plan (QHP). If a Non-Formulary Exception request is made and approved, the compound medication must be obtained from a retail pharmacy that has been credentialed to dispense compound medications. Compound medications are not available through the mail order pharmacy benefit.

Definitions:

Formulary:
The list of medications BCBSAZ has designated as covered under the QHP Pharmacy Benefit. Medications not on the Formulary are not covered unless BCBSAZ authorizes a Formulary Exception for a Non-Formulary Medication. BCBSAZ decides which medications are on the Formulary. The list of Formulary medications can change at any time where a medication may be added or removed from the Formulary.

Formulary Exception:
Occurs when BCBSAZ has authorized coverage of a Non-Formulary Medication for a member. BCBSAZ decides whether to authorize Formulary Exceptions for coverage of Non-Formulary Medications.

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Non-Formulary Medications:

Medications not included on the Formulary. These medications are not covered under the QHP Pharmacy Benefit unless BCBSAZ authorizes an exception. Members may ask the prescribing provider to request that BCBSAZ make a Formulary Exception for a Non-Formulary Medication. BCBSAZ decides which medications are Non-Formulary Medications and whether to authorize Formulary Exceptions for Non-Formulary Medications.

National Compendia:

American Hospital Formulary Service
Micromedex/DrugDex
Elsevier Gold Standard's Clinical Pharmacology compendium
United States Pharmacopeia
National Formulary Monograph
Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services

Resources:

Food and Drug Administration: Bulk Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act. 503A Lists 1-4. https://www.fda.gov/media/94155/download Accessed December 30, 2020.

Food and Drug Administration: Bulk Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act. 503B Lists 1-4. https://www.fda.gov/media/94164/download Accessed December 30, 2020.