An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

COMPOUNDED MEDICATION

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

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

  1. Medical necessity or justification for use must be submitted with the request by prescriber office and treatment goal(s) with proposed duration of use must be specified within the request

  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 per FDA label, intolerance, or is not a candidate for 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 prior authorization, all criteria for prior authorization 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 **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

- **Criteria for continuation of coverage (renewal request):** Compounded medication is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual has achieved and maintains goal(s) that were specified in the original request and as such requires continued therapy

2. Individual's condition has not progressed or worsened while on therapy defined as follows:
    a. There is evidence of disease progression
    b. There is no evidence of efficacy, disease stability and/or improvement
    c. There is evidence individual has developed significant unacceptable adverse drug reaction(s) that may exclude continued use

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

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Compounded 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 compounded 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 prescriptions are only available through the retail pharmacy benefit. Compounded prescriptions are not available through the mail order pharmacy benefit.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

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 Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Updated September 27, 2024. Available at: https://www.fda.gov/media/94155/download. Accessed December 27, 2024.

Food and Drug Administration: Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act. Updated May 20, 2024. Available at: https://www.fda.gov/media/94164/download. Accessed December 27, 2024.

Food and Drug Administration: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Guidance for Industry. January 2017. Available at: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov). Accessed December 27, 2024.

Food and Drug Administration: Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. January 2018. Available at: Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov). Accessed December 27, 2024.