

PHARMACY COVERAGE GUIDELINE

COMPOUND MEDICATION – NON-FORMULARY (AFFORDABLE CARE ACT (ACA) PLANS)

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/or 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.

Medical Necessity Requirements for COMPOUND MEDICATION – NON-FORMULARY (Affordable Care Act (ACA) Plans)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a licensed healthcare provider

Indication

- Diagnosis must be clearly specified

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Age Requirement

- Is consistent with FDA approved label

Baseline Clinical Evaluation

- The compound prescription meets **ONE** of the following:
 - Requested compound must not already be commercially available in the same dosage form, route of administration, or requested dose from any pharmaceutical manufacturer
 - Compound contains an ingredient(s) that is/are in short supply
 - Due to severe intolerance or severe hypersensitivity to inactive ingredient(s), 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 (Documentation of intolerance or hypersensitivity must be sent with request)
 - There is a need for a unique dosage form or concentration due to age, weight, or inability to take solid dosage form
- For ingredient(s) that normally require prior authorization **ALL** criteria for prior authorization of the ingredient(s) are met
- Must contain at least one federal legend drug
- Active ingredients must be FDA approved or supported by national compendia or peer reviewed literature for:
 - Diagnosis
 - Route of delivery
 - Therapeutic amounts
 - Safety and effectiveness
 - Proposed duration of therapy

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Ingredients must not be **ANY** of the following:
 - Used for non FDA approved use for the diagnosis
 - Investigational or experimental
 - Not FDA approved for compounding
 - Removed from the market due to safety or effectiveness concerns
 - Compounded for convenience

Additional Requirements

- Medical necessity or justification for use must be submitted with the request
- Treatment goals and proposed duration of use must be included in the request
- Follows plan specific Benefit Design
- Use is not for cosmetic purposes
- Use is not considered manufacturing or distribution

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Documentation Requirements

- A completed request form must be submitted including:
 - Chart notes
 - Lab results
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
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Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications

- Continues to be seen by a licensed healthcare provider

Clinical Response

- Achieved and maintains treatment goals that were specified in the original request
- The request is for the same compound as originally approved (same dose form, strength, ingredients, etc.)
- **ALL** of the following:
 - Condition has not progressed or worsened
 - Evidence of efficacy, disease stability, or improvement
 - No significant unacceptable adverse drug reactions

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Ingredients must not be **ANY** of the following:
 - Used for non FDA approved use for the diagnosis
 - Investigational or experimental
 - Not FDA approved for compounding
 - Removed from the market due to safety or effectiveness concerns
 - Compounded for convenience
- No new contraindications or exclusions to continued use

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

ORIGINAL EFFECTIVE DATE: 03/16/2017 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/15/2024

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Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
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Criteria for Off-Label Use Requests:

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
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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 an Affordable Care Act (ACA) Plan. 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:

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

Formulary:

The list of medications BCBSAZ has designated as covered under the ACA 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.

Non-Formulary Medications:

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Medications not included on the Formulary. These medications are not covered under the ACA 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 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. Re-evaluated January 05, 2026.

Food and Drug Administration: Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act. Updated March 21, 2025. Available at: <https://www.fda.gov/media/94164/download>. Accessed January 05, 2026.

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 2025. Available at: [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry \(fda.gov\)](https://www.fda.gov/oc/interim-policy-on-compounding-using-bulk-drug-substances-under-section-503a-of-the-federal-food-drug-and-cosmetic-act-guidance-for-industry). Accessed January 05, 2026.

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 \(fda.gov\)](https://www.fda.gov/oc/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). Accessed December 27, 2024. Re-evaluate January 05, 2026.