

PHARMACY COVERAGE GUIDELINE

Non-Formulary Medications Coverage Guideline (for Closed Formularies)

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 Non-Formulary Medications

Purpose: This coverage guideline is used to address non-formulary medications that do not have a specific BCBSAZ drug coverage guideline or drug specific step therapy criteria.

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician specializing in the diagnosis or in consultation with a physician in the clinically appropriate specialty

Indication

- Diagnosis is consistent with the FDA approved product labeling

ORIGINAL EFFECTIVE DATE: 05/21/2020 | ARCHIVE DATE: | LAST REVIEW DATE: 05/15/2025 | LAST CRITERIA REVISION DATE: 05/16/2024

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Non-Formulary Medications Coverage Guideline (for Closed Formularies)

Age Requirement

- Age consistent with FDA approved product labeling

Baseline Clinical Evaluation

- All required baseline tests cited in FDA approved product labeling have been completed before starting treatment
- Requested dosage for use is consistent with the FDA approved product labeling
- Duration of use is consistent with the FDA approved product labeling

Alternative Therapies

- Failure, contraindication, or intolerance to **THREE** or more formulary medications approved by the FDA for the indication or diagnosis (if available)

Brand Specific Criteria

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

Safety

- Product has established safety and efficacy for the condition or diagnosis
- No FDA-label contraindications or other significant exclusions to use
- No significant interacting drugs

Additional Requirements

- Individual does not have a conflicting benefit exclusion

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

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 physician specializing in or is in consultation with a clinically appropriate specialty

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Non-Formulary Medications Coverage Guideline (for Closed Formularies)

Clinical Response

- Has benefited from therapy and remains at high risk and as such requires continued use
- Positive clinical response defined as **ALL** the following:
 - No evidence of disease progression
 - No significant unacceptable adverse drug reactions
 - Documented evidence of efficacy, disease stability and/or improvement
 - Achieved and maintains most activities of daily living

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (when 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

- No FDA-label contraindications or other significant exclusions
- No significant interacting drugs

Additional Requirements

- Individual does not have a conflicting benefit exclusion

Documentation Requirements

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

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:

BCBSAZ benefits require that medications are FDA approved. Non-Formulary medication requests must include the medication name, dose, frequency, length of therapy anticipated, other agents tried previously with information on failure or ineffective treatments or adverse drug events or contraindications or non-adherence, disease or condition being treated including the severity, and all applicable laboratory and other test results. Additional information submitted by the prescriber will also be reviewed (e.g. clinical articles from the literature, clinical guidelines, etc.).

Definitions:

FDA: Food and Drug Administration

Medication Product Labeling: Manufacturer FDA approved product information

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

Resources:

FDA-approved product labeling guideline

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

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