

PHARMACY COVERAGE GUIDELINE

STEP THERAPY

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 STEP THERAPY MEDICATIONS

Criteria for Initial Therapy:

Age Requirement

- Age is appropriate for the requested Step Therapy Medication

Baseline Clinical Evaluation

- A confirmed diagnosis that is treated by a Step Therapy Medication

Alternative Therapies

- Failure, contraindication, intolerance to drugs listed in the Step Edit Criteria referenced in the **Step Therapy Drug List** ([click here](#))

ORIGINAL EFFECTIVE DATE: 01/18/2018 | ARCHIVE DATE: | LAST REVIEW DATE: 05/21/2026 | LAST CRITERIA REVISION DATE: 05/18/2023

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Safety

- Requested dosage and duration for use is consistent with the FDA approved product labeling or set quantity limits

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

Clinical Response

- No evidence of disease progression
- Documented evidence of efficacy, disease stability, and/or improvement
- No significant unacceptable adverse drug reactions

Adherence

- Adherence to the prescribed therapy regimen has been documented

Safety

- No significant drug to drug interactions
- No contraindications or adverse drug effects that may exclude continued use

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
-

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

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2. Off-Label Use of Cancer Medications

Description:

Prescription Drug Benefit plans apply various management strategies that put limitations on certain medications. These limitations may include, but are not limited to, prior authorization (or prior certification), quantity limits and step therapy.

BCBSAZ determines which medications are subject to limitations based upon medication product labeling, nationally recognized compendia, or guidelines, and established clinical trials that have been published in peer reviewed professional medical journals. Medication limitations are subject to change at any time without prior notice.

Step Therapy is the practice of beginning a preferred drug for a medical condition before progressing to another therapy. It requires trying a Step Therapy Drug A before getting Step Therapy Drug B. Step therapy guidelines are developed and reviewed by a panel of practicing physicians and pharmacists.

Step therapy is an automated process. When a prescription for a step therapy medication (drug "B") is presented to a pharmacy, an automated check of the member's prescription history occurs. If the system finds that the member has received a drug "A", the prescription for the step therapy medication drug "B" will automatically process.

If the system does not find the drug "A" in the member's prescription history, a prior authorization will be necessary.

Prior authorization allows providers to submit medical record documentation of failure, intolerance, or contraindications that may exist for drug "A" which would suggest approval to bypass use of the preferred product. BCBSAZ will review the information presented and if approved, an authorization for drug "B" can be entered into the member's pharmacy record.

BCBSAZ maintains a list of medications that require step therapy and is available on www.azblue.com/pharmacy by selecting the appropriate plan option, or click [here](#).

Definitions:

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