BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

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 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:** Step Therapy Medication is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Individual age is appropriate for the requested Step Therapy Medication.

  2. There is a confirmed diagnosis that is treated by a Step Therapy Medication

  3. Individual has documented failure, contraindication, intolerance, or is not a candidate for drugs listed in **Step Edit Criteria** referenced in **Step Therapy Drug List** (click here)

  4. Requested dosage and duration for use is consistent with the FDA approved product labeling or set quantity limits for the requested Step Therapy Medication

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

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Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Step Therapy 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's condition has responded while on therapy with response defined as the following:
     a. No evidence of disease progression
     b. Documented evidence of efficacy, disease stability and/or improvement
     c. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
  2. Individual has been adherent with the medication
  3. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
  4. There are no significant interacting drugs

  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:

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 authorization), 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 drug for a medical condition with a preferred drug 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.