An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE:**	**1/18/2018**
SECTION: DRUGS	**LAST REVIEW DATE:**	**2/17/2022**
	LAST CRITERIA REVISION DATE:	**2/17/2022**
	ARCHIVE DATE:	

STEP THERAPY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

STEP THERAPY

Criteria:

- **Criteria for initial therapy:** Step Therapy Medication is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with the appropriate specialist for the condition being treated

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

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

  4. **ALL** of the required baseline tests cited in the FDA approved labeling for the requested Step Therapy Medication have been completed before initiation of treatment with continued monitoring as clinically appropriate

  5. Individual has failure, contraindication or intolerance to drugs listed in **Step Edit Criteria** referenced in **Step Therapy Drug List** (click here)

  6. Requested dosage and duration for use is consistent with the FDA approved product labeling for the requested Step Therapy Medication

  7. There are **NO** FDA-label contraindications

  8. There are no significant interacting drugs

  Initial approval duration: 6 months

- **Continuation of coverage (renewal request):** Step Therapy Medication is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with the appropriate specialist for the condition being treated

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. Documented evidence of efficacy, disease stability and/or improvement
        iii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use

5. There are no significant interacting drugs

Renewal approval 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, precertification (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 precertification will be necessary. Precertification 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.