BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

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 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 precertification 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.

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:

➢ **Criteria for initial therapy:** A **Non-Formulary Medication** is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a physician in the clinically appropriate specialty

2. Individual does not have a conflicting benefit exclusion

3. Age of individual is consistent with the FDA approved product labeling

ORIGINAL EFFECTIVE DATE: 05/21/2020 | ARCHIVE DATE: | LAST REVIEW DATE: 05/19/2022 | LAST CRITERIA REVISION DATE: 02/16/2023

4. Indication for use or diagnosis is consistent with the FDA approved product labeling

5. Requested dosage for use is consistent with the FDA approved product labeling

6. Duration of use is consistent with the FDA approved product labeling

7. The individual has received and completed **ALL** of the required **baseline tests** cited in the FDA approved product labeling before initiation of treatment and with continued monitoring of the individual as clinically appropriate

8. Individual has failure, contraindication per FDA label, or intolerance to **THREE or more** formulary medications approved by the FDA for the indication or diagnosis if available

9. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

10. Product has established safety and efficacy for the condition or diagnosis

11. There are **NO** FDA-label contraindications and other significant exclusions to its use

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request): Non-Formulary 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 continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a physician in the clinically appropriate specialty

2. The individual has benefited from therapy and remains at high risk and as such requires continued use

3. Individual's condition has responded while on therapy with response defined as **ALL** of the following:
   a. No evidence of disease progression
   b. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
   c. Documented evidence of efficacy, disease stability and/or improvement
   d. Achieved and maintains most activities of daily living

4. Individual has been adherent with the medication

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual has not developed any FDA-label contraindications or other significant exclusions to its continued use

7. 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:

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.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.