BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINE**

# General Coverage Guideline (For Medication Without Drug Specific Guideline)

**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: Medication** and/or generic equivalent (if available) are 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. Individual's age is consistent with the FDA approved product labeling
  4. Agent's indication for use is consistent with the FDA approved product labeling
  5. Agent's requested dosage for use is consistent with the FDA approved product labeling

6. Agent's duration of use is consistent with the FDA approved product labeling

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

9. Individual meets **ONE** of the following:
    a. Individual has failure, contraindication, intolerance, or is not a candidate for **TWO** alternative medications with similar mechanism of action to the requested medication
    b. If there are no medications with similar mechanism of action available, individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** alternative medications that are medically acceptable to treat the member's condition (see Definitions section)
    c. Individual has failure, contraindication per FDA-label, intolerance, or is not a candidate for an FDA approved generic or biosimilar equivalent to the medication requested (if available)
    d. There are no alternative medications that are medically acceptable to treat the individual's condition

10. Agent's use has established safety and efficacy for the condition or diagnosis

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

12. There are no significant interacting drugs

**Initial approval duration**: 6 months (or as subject to limitations found in the FDA-approved product labeling)

- **Criteria for continuation of coverage (renewal request): Medication** and/or generic equivalent (if available) are 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 physician specializing in the patient's diagnosis or is in consultation with a physician in the clinically appropriate specialty

2. Individual's condition has responded while on therapy with response defined as **ALL** of the following:
    a. There is no evidence of disease progression
    b. There is documented evidence of efficacy and/or improvement
    c. There is evidence the individual achieved and maintains most activities of daily living

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. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is 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. There are no significant interacting drugs

**Renewal duration**: 12 months (or as subject to limitations found in the FDA-approved product labeling)

- 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. General medication requests for agents that require prior authorization but do not have a specific pharmacy coverage guideline must include the medication name, dose, frequency, route of administration, 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.).

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**Definitions:**

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

**FDA**: Food and Drug Administration

**Medication Product Labeling**: Manufacturer FDA approved product information

**Medically acceptable**: Medications that may be considered as medically acceptable alternative medications should meet the standards for safety and efficacy for the indication requested as defined below:

- Medication is FDA approved for the same indication
- Medication is recognized to be safe and effective for indication requested and is supported by **ONE** of the nationally recognized compendia, guidelines or literature:
  - American Hospital Formulary Service Clinical Drug Information with narrative text of “supportive”
  - IBM Micromedex compendium that meets **ALL** of the following:
    - Strength of Recommendation of Class I or IIa
    - Strength of Evidence Category A or B
    - Strength of Efficacy Class I or Iia (evidence favors efficacy)
  - Elsevier Gold Standard’s Clinical Pharmacology compendium with narrative text of “supportive”

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- Wolters Kluwer Lexi-Drugs with use listed as “off-label, evidence level A”
- Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services
- National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
- At least **TWO** articles from major peer reviewed professional medical journals that have recognized, based on scientific or medical criteria, the safety and effectiveness for the exception on medical limitation for age, gender, quantity, or dosage

**Resources:**

FDA-approved product labeling guideline

Off Label Use of Cancer Medications: A.R.S. §§ 20-826® & (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