

PHARMACY COVERAGE GUIDELINE

MEDICATION LIMITATION FOR AGE, GENDER, QUANTITY, AND DOSAGE

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 **MEDICATION LIMITATION FOR AGE, GENDER, QUANTITY, AND DOSAGE**

Criteria for Initial Therapy:

Indication

- Diagnosis and treatment plan must include rationale for exception request related to age, gender, quantity, or dosage limitation

Baseline Clinical Evaluation

- Supporting evidence for exception must be recognized as safe and effective by **ONE** of the following:
 - American Hospital Formulary Service Clinical Drug Information with narrative text of “supportive”
 - IBM Micromedex compendium meeting ALL of the following:

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1. Strength of Recommendation: Class I or IIa
2. Strength of Evidence: Category A or B
3. Strength of Efficacy: Class I or IIa
 - Elsevier Gold Standard’s Clinical Pharmacology compendium with narrative text of “supportive”
 - 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 supporting safety and effectiveness of the exception

Alternative Therapies

- Preferred formulary products used within the specified limitations were not effective and cannot be used

Safety

- No FDA labeled contraindications for the requested drug
- No significant interacting drugs

Additional Requirements

- There are no benefit or contract exclusions that apply

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

- Documented evidence of efficacy, disease stability, and/or improvement

Adherence

- Adherence to the prescribed therapy regimen has been documented

Safety

- No new contraindications per FDA label
- No significant adverse drug effects

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- No significant interacting drugs

Additional Requirements

- There are no benefit or contract exclusions that apply

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
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Description:

Medications are subject to limitations, including but not limited to, quantity, age, gender, and dosage. 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. Providers may submit an exception request when medication limitations are exceeded or not met. However, a request is not a guarantee of coverage. Applicable benefit limitations and exclusions of the member's specific benefit plan may apply.