BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

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 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:** An exception request on **medication limitation for age, gender, quantity, or dosage** is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Provider submits a diagnosis and treatment plan that includes the rationale for the exception on medication limitation for age, gender, quantity, or dosage

2. Preferred formulary products, used in accordance with medication limitation for age, gender, quantity, or dosage, were not effective in controlling the condition and cannot be used

3. Evidence that supports the reason for making an exception on medication limitation for age, gender, quantity, or dosage, is recognized as safe and effective is supported by **ONE** of the nationally recognized compendia, guidelines, or literature:
    a. American Hospital Formulary Service Clinical Drug Information with narrative text of "supportive"

b. IBM Micromedex compendium that meets **ALL** of the following:
   i. Strength of Recommendation of Class I or IIa
   ii. Strength of Evidence Category A or B
   iii. Strength of Efficacy Class I or IIa (evidence favors efficacy)
c. Elsevier Gold Standard's Clinical Pharmacology compendium with narrative text of "supportive"
d. Wolters Kluwer Lexi-Drugs with use listed as "off-label, evidence level A"
e. Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services
f. National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
g. 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

4. There are no FDA-label contraindications for use of the requested drug

5. There are no significant interacting drugs

6. There are no benefit or contract exclusions that apply

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request): Medication limitation for age, gender, quantity, or dosage** 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 documented evidence of efficacy, disease stability and/or improvement

2. Individual has been adherent with the medication

3. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use

4. There are no benefit or contract exclusions that apply

5. There are no significant interacting drugs

Renewal duration: 12 months

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.

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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.

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