BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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MEDICATION LIMITATION FOR AGE, GENDER, QUANTITY, AND DOSAGE

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.

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.**

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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 with of **ALL** of 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:
     - American hospital Formulary Service with narrative text of "supportive"
     - Micromedex compendium that meet **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"
     - 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
     - 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 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** of the following criteria are met:

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - No evidence of disease progression
       - Documented evidence of efficacy, disease stability and/or improvement

  2. Individual has been adherent with the medication

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

4. There are no benefit or contract exclusions that apply

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.

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.