

# Pharmacy Prior Authorization Quantity or Age Limit Exception Criteria

# **Quantity Limit Exceptions**

Standard quantity limits are designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request. This applies to requests that exceed the quantity limits for loading doses or other special situations.

#### **Age Limit Exceptions**

Medications may have age restrictions based on approved guidelines, policies, and protocols. Age limits are often specified in drug or drug class-specific criteria, which detail the requirements for medications based on age. Drug regimens outside FDA-approved age limits can be reviewed individually upon request.

### **Quantity Limit Prior Authorization Guidelines:**

- The requested drug/product is used for an FDA-approved indication or a medically accepted indication as defined by one of the following standard reference compendia:
  - o American Hospital Formulary Service Drug Information (AHFS-DI)
  - Thomson Micromedex DrugDex
  - Clinical Pharmacology
  - Wolters Kluwer Lexi-Drugs
  - Peer-reviewed published medical literature indicating that sufficient evidence exists to support use
- The prescribed dosage and quantity are consistent with FDA-approved labeling or compendia-supported dosing guidelines.
- At least one of the following criteria is met:
  - The dose and frequency requested is for a loading dose to initiate therapy.
  - The patient needs a higher quantity due to dosing by weight or body surface area (Patient's weight and/or BSA must be provided).
  - Additional quantities of the lower strength are required due to intolerance to the higher strength (Rationale must be provided).
  - A greater quantity is needed to adjust the dose or frequency due to a drug interaction (Specific drug-drug interaction must be provided).
  - The request is for continuation of therapy at the current dose where the patient is stable and not experiencing adverse side effects (Start date of therapy on requested dose must be provided).
  - The patient tried and failed lower doses and now requires a higher dose (Failed regimens must be provided).

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# **Age Limit Prior Authorization Guidelines:**

Authorization may be granted when all the following criteria are met:

- The drug/product is used for an FDA-approved or medically accepted indication as defined in standard reference compendia (e.g., AHFS-DI, Micromedex DrugDex, Clinical Pharmacology, Lexi-Drugs, or peer-reviewed medical literature).
- The prescribed dose and quantity are within FDA-approved labeling or compendia-supported guidelines.
- All relevant documentation (e.g., lab values, treatment plan, medical chart notes) is provided.
- Rationale for why the drug is necessary for a patient of this age is provided.
- Rationale for why formulary alternatives are not appropriate is provided, when applicable.

### **Coverage Duration:**

• Up to 12 months as clinically appropriate

#### Renewal:

• 1 year

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