

Effective Date: 7/2018
Revised: 11/2019
Reviewed: 7/2018, 11/2019, 04/2020, 1/2021, 1/2022, 1/2023
Scope: Medicaid

Age Restriction Exception Criteria

POLICY

I. CRITERIA FOR APPROVAL

An authorization may be granted when all the following criteria are met:

- A. The requested drug/product is being used for an FDA-approved indication or a medically accepted indication as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or peer-reviewed published medical literature indicating that sufficient evidence exists to support use.
- B. The prescribed dose and quantity fall within the FDA-approved labeling or within compendia-supported dosing guidelines.
- C. All relevant documentation (e.g. lab values, treatment plan, medical chart notes) is provided.
- D. Rationale provided for why the use of the requested drug is necessary for a patient of this age.
- E. Rationale provided for why formulary alternatives (e.g. alternative dosage forms) are not appropriate, when applicable.

II. CONTINUATION OF THERAPY

- A. Patient meets all initial criteria.
- B. Patient is tolerating treatment and is not experiencing any unacceptable toxicity from the drug.
- C. Patient has disease stabilization or improvement in disease (as defined by established clinical practice guidelines).

III. COVERAGE DURATION

- Up to 12 months as determined by FDA guidance and internal policies and procedures