Effective Date: 7/2018 Revised: 11/2019 Reviewed: 7/2018, 11/2019

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 compendiasupported dosing guidelines.
- C. Rationale provided for why the use of the requested drug is necessary for a patient of this age.
- D. Rationale provided for why formulary alternatives (e.g. alternative dosage forms) are not appropriate, when applicable.

II. COVERAGE DURATION

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



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