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Scope: Medicaid

## Step Therapy 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 first-line agents, including the generic and biosimilar alternative, if available are not appropriate for the patient.

#### II. COVERAGE DURATION

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

#### III. REFERENCES

1. NHPRI Formulary Management Policy and Procedure.