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Scope: Medicaid

## Prior Authorization Global 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.
  - a. Medication is not being used for an oncology or hematology related indication.
- 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. The patient has experienced an inadequate treatment response or intolerance to all formulary first-line agents, including the generic and biosimilar alternative, if available.

#### II. CONTINUATION OF THERAPY

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

#### III. COVERAGE DURATION

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

#### References

- 1. NHPRI Formulary Management Policy and Procedure.