Effective Date: 4/2019
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Non-Formulary 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. One of the following criteria is met:
   a. The patient has experienced an inadequate treatment response or intolerance to two comparable formulary alternatives for the same indication, including the generic and biosimilar alternative, if available.
   b. If there are less than two comparable formulary alternatives available for the same indication, the patient has experienced an inadequate treatment response or intolerance to all of the formulary alternatives, including the generic and biosimilar alternative, if available.
   c. If there are no comparable formulary alternatives, rationale provided for why requested drug/product is medically necessary.

D. For Commercial autoimmune non-formulary exception requests (e.g., Taltz, Tremfya, Otezla, Bimzelx, Ilumya, Sotyktu, Skyrizi for Psoriasis or Psoriatic Arthritis, etc.):
   a. The patient has tried, failed, or has a contraindication to all products (at least one product of each mechanism of action e.g., an anti-TNF, an IL-12/23 inhibitor, an IL-17 inhibitor, etc.) indicated to treat the patient's autoimmune condition available on the formulary

II. CONTINUATION OF THERAPY

A. Patient meets all initial criteria in section I.
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

IV. REFERENCES

1. NHPRI Formulary Management Policy and Procedure.

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