Effective Date: 4/2019
Reviewed: 4/2019, 11/2019, 06/2020, 02/2021, 02/2022, 01/2023, 01/2024 Scope: Medicaid, Commercial

Quantity Limit 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. At least one of the following criteria is met:
   a. The dose and frequency requested is for a loading dose for the initiation of therapy.
   b. The patient is being prescribed a drug dosed by weight or body surface area and requires a greater quantity to achieve the appropriate dose [Patient's weight and/or BSA must be provided].
   c. The patient requires additional quantities of the lower strength of this medication due to intolerance to the recommended maintenance dosing/frequency using the higher strength of the medication [Rationale must be provided].
   d. The patient requires a greater quantity to adjust the dose or frequency of administration due to a drug interaction [Specific drug-drug interaction must be provided].
   e. The request is for continuation of therapy on the requested dose where patient is stable and not experiencing any adverse side effects, [Start date of therapy on requested dose must be provided].
   f. The patient tried and failed lower doses of requested medication and now requires a higher dose [Failed regimens must be provided].

II. COVERAGE DURATION

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

References

1. NHPRI Formulary Management Policy and Procedure

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