

## SPECIALTY POST LIMIT QUANTITY EXCEPTION CRITERIA

### I. PROGRAM DESCRIPTION

Coverage is provided for an amount of drug sufficient for most members based on the most common uses of the drug. The submitted prescription is covered up to this standard limit without a review process. In situations where an additional quantity of drug is needed to adequately treat the member, prior authorization is required to determine if clinical exceptions are met.

Coverage for an additional quantity of drug is provided for duration sufficient for most uses (e.g., shorter period of time to accommodate loading doses or dose titration when a member requires additional amounts to adequately treat his/her condition).

In situations where coverage for additional quantities is not approved through the prior authorization process, an appeals process exists to review specific or unique cases where additional drug may be necessary.

### II. RATIONALE

The intent of this program is to provide coverage for quantities sufficient for treatment for most members based on the most common uses of the drug. Quantity limits are based on dosage recommendations in product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. In situations where greater amounts of drug are needed, prior authorization criteria allow approval of these quantities based on clinical exceptions such as to accommodate loading doses, compendial supported dosing, drug interactions, or dosing by body weight or body surface area, and to allow for dose adjustments using a particular strength of the drug, as applicable.

### III. CRITERIA FOR APPROVAL

The use of medication at the requested quantity is supported by the manufacturer's prescribing information or dosing guidelines found in the compendia or current literature (e.g., AHFS, Micromedex DrugDex, NCCN compendia, current treatment guidelines) and the member meets the criteria set A, B or C.

- A. Authorization for a quantity up to the exception limit may be granted for up to 90 days for initiation of treatment at a higher dose or frequency of administration (e.g., loading dose).
- B. Authorization for a quantity up to the exception limit may be granted for up to 6 months when a greater quantity is necessary to adjust the dose using a lower strength due to intolerance to the recommended maintenance dose.
- C. Authorization for a quantity up to the exception limit may be granted for up to 12 months or for the remaining duration of any other existing prior authorization (e.g., Specialty Guideline Management) in the following situations:
  - 1. Member is prescribed a drug dosed by weight or body surface area and requires a greater quantity to achieve the appropriate dose OR
  - 2. A greater quantity is necessary to accommodate a higher dose following an inadequate response OR
  - 3. A greater quantity is necessary for a compendial use or an FDA-approved indication OR
  - 4. A greater quantity is necessary to adjust the dose or frequency of administration to account for a drug interaction.

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5. 5. A greater quantity is necessary to accommodate for a member's pharmacokinetic profile (e.g., extensive or intermediate CYP2D6 metabolizer).

#### IV. COVERED QUANTITIES

Coverage is provided without prior authorization up to the standard limits. Coverage of an additional quantity may be provided up to the exception limit with prior authorization. These limits are specified in the Specialty Quantity Limit Program policies for the applicable products.