

Aetna Policy: Applying Quantity Limitations to Medications (Non-Medicare Prescription Drug Plan)

PURPOSE:

The purpose of this policy is to establish a policy for situations where quantity limitations will apply to drugs and the circumstances that will be considered to approve requests for additional quantities. Quantity limit programs are part of Aetna's suite of precertification programs and are developed to encourage appropriate and cost-effective prescribing of drugs in accordance with labeling approved by the Food and Drug Administration (FDA), manufacturer and peer-reviewed literature.

MEDICAL EXCEPTION COVERAGE POLICY

Quantity limits are designed to promote appropriate and efficient drug use, enhance patient safety and discourage misuse, waste and abuse.

Quantity limits are based on generally accepted pharmaceutical guidelines, FDA labeling, efficient dosing regimens and dosing recommendations. The following types of quantity limits are in place:

- Dose Efficiency Edits – Limits coverage of medications to a specific number of doses per day based upon common prescribing practices and FDA labeling. Examples include one dose per day for drugs that are approved for once-daily dosing, two doses per day of drugs that are dosed twice daily.
- Maximum Daily Dose – Coverage is provided up to a specific limit per day, such as a number of milligrams. A message is sent to the pharmacy if a prescription exceeds the highest allowed dose.
- Quantity Limits Over Time – Limits coverage of prescriptions to a specific number of units in a defined period of time. Examples include one course of therapy in a year.
- Quantity limits per Fill – A member may obtain a specific amount of medication each time the prescription is filled. A medication may be filled more than once per month per physician instruction. Each fill requires the applicable copay or coinsurance based on the member's plan. Payment beyond the covered quantity is the member's responsibility. An example is two metered dose inhalers for the treatment of asthma are covered per fill.

Quantity limit drugs may be covered up to the amount indicated. To get coverage for amounts in excess of the listed quantity limit, the prescribing physician, the patient or the person appointed to manage the patient's care may request a medical exception.

Medical exceptions may be considered in situations where any of the following apply:

- The patient requires additional quantities of medication due to dosage titration up to the FDA approved maximum daily dose.
- The daily dosage and dosing frequency for the indication are within the FDA-approved labeling.
- The dosage for the indication is supported by one of the standard pharmacy compendia.
- The dosage has been demonstrated to be safe and effective for this indication as demonstrated by 1 or more well-designed controlled clinical trials in the peer-reviewed published medical literature.
- The patient requires additional quantities of medication to complete a course of therapy.
- The prescriber has provided supporting documentation (written or verbal) indicating that the number of doses available under a quantity restriction for the prescription drug:

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- a. Has already been ineffective in the treatment of the enrollee's disease or medical condition (i.e. the enrollee has already tried and failed the covered quantity), AND/OR
- b. Based on sound evidence (clinical, medical, scientific), the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, the quantity covered by the plan is likely to:
 - i. Be ineffective, AND/OR
 - ii. Adversely affect the drug's effectiveness, AND/OR
 - iii. Adversely affect the patient's compliance.

Coverage for additional quantities of medication is provided on an individual basis and may be approved if one of the conditions above is met.