AETNA BETTER HEALTH OF PENNSYLVANIA
Clinical Practice Guideline

Prior Authorization Review Panel

MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health	**Submission Date**:8/1/2021
Policy Number:	**Effective Date:** ASAP **Revision Date:** 5/2021
Policy Name: Quantity Level Limit(s)	
Type of Submission – Check all that apply: ☐ **New Policy** X **Annual Review – No Revisions** ☐ **Revised Policy**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Thank you.	

Last Review: 5/2021
Previous PARP Approval 6/2020
Current PARP Approval: 09/2021

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Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
Natalie Nkurunziza, PharmD	

Prior Authorization guideline for Quantity Level Limits (QLL)

Prescription requests that exceed established Quantity Level Limits will require prior authorization.

Drugs that are subject to additional utilization management requirements (for example, non-preferred, clinical prior authorization, and step therapy) must meet the clinical criteria and medical necessity for approval in addition to any established Quantity Level Limits.

Approval of Quantity Level Limits exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed.

Please refer to the Quantity Limits document on the Aetna Better Health website for the list of drugs are subject to quantity limits/daily dose limits.

Authorization Criteria for Quantity Limit Exceptions:

A. For Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:

1. Dose to be titrated down by the prescriber (*3-month limit*)

   OR

2. Member had an inadequate response to the same medication at a lower dosage and the inadequate response is not due to medication non-adherence

   AND

3. Member is tolerating the medication at a lower dosage

   AND

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4. Request meets one of the following:
    i. Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication
    ii. A published, randomized, double blind, controlled trial demonstrating the safety and efficacy of the requested dose for the indication is submitted with the request

B. For Quantities that do not Exceed FDA Maximum Dose (*Dose Optimization*), documentation of one of the following:

1. Patient had an inadequate response or intolerable side effects to the optimized dose
2. There is a manufacturer shortage on the optimized strength
3. Dose to be titrated/dose optimized by the prescriber (*3-month limit*)
4. Member is unable to swallow tablet/capsule due to size, and cannot be crushed
5. Effect of medication is wearing off between doses
6. Member cannot tolerate entire dose in one administration

C. For Quantities for Medications that do not have an established FDA Maximum Dose:

a. Patient has had an inadequate response to the same medication at a lower dosage
b. Patient is tolerating the medication at a lower dosage
c. Requested dose is considered medically necessary

Authorization and Limitations

Initial Approval: 3 months for dose titrations; 1 year for all other approvals
Renewal: 1 year

Additional Information:

Increased quantity levels are NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**

- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. Any determinations that may result in a denied request will be made by the Medical Director. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.