Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Quantity Limits***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***June 2000 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *May 2019*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the pharmacy quantity limits process.

DEFINITIONS

Food and Drug Administration (FDA): a federal agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, vaccines and other biological products, medical devices, regulating food for commercial consumption, cosmetics, dietary supplements, and products that give off radiation.

POLICY

It is the policy of the Health Plan to promote appropriate utilization of specific drugs with potential for misuse, that have limited indications and/or safety issues, and that have a maximum recommended dosage by the Food and Drug Administration (FDA). Quantity limits are enforced on specific medications.

PROCEDURE

Quantity Limits
Quantity limits are established based on FDA approved dosing and are listed in the plan formulary documents.

Once Daily Dosing Limits
Medications that are available in a larger strength and FDA approved for once daily dosing instead of multiple doses of the smaller strength are limited to one unit per day for a 30-day supply. For example, if a medication is available in a 20mg and 40mg strength and the member is instructed to take two 20mg per day, the health plan requests that the pharmacy dispense the 40mg tablet.

FDA Maximum Limits
In accordance with industry safety standards, the health plan has in place maximum dosing limits at point of service to promote safe and effective use of medications.

For all drugs with a quantity limit in place:
The prescriber may submit a supporting statement for review as a coverage determination for a quantity limit exception if more than allowed by the plan is considered medically necessary.

Initial Authorization Criteria:
Must meet all of the criteria listed below:

- Requested medication must be used for an FDA-approved indication OR an indication supported by the pharmacopendia/current literature (e.g., AHFS, Micromedex, current accepted guidelines)
- Prescribed quantity must fall within manufacturer's dosing guidelines or supported by the pharmacopendia/current literature

The provider must include a supporting statement that indicates the following:

- A number of doses under the quantity limit has been ineffective in treating the current condition, is likely to be ineffective, or would adversely affect the drug's effectiveness or the member's ability to take the drug
- If the member is using multiple doses of a medication that is FDA approved for once daily dosing, documentation that the member has failed to tolerate once daily dosing of the total daily dose requested is required

Reauthorization Criteria:

All quantity limit exception renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy above the designated quantity limit. Authorization may be extended at 1-year intervals based upon meeting initial criteria AND chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy at the higher dose.

Limitations:

- Not all medications with quantity limits are formulary agents for Commercial. If coverage of a non-formulary medication is approved through the formulary exception process, then quantity limits may apply. Please refer to Policy & Procedure RX.008.2 Exceptions Due to Medical Necessity - Commercial.
    - For example, all diabetes test strips have imposed quantity limits regardless of formulary status

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
QL updates	*01/16, 05/16, 06/16, 10/16, 12/16, 07/17, 11/17, 01/18, 11/18*
Annual review	*02/16, 02/17, 02/18, 02/19*
Updated policy	*12/18*
Added reauthorization criteria	*05/19*