Clinical Policy: Quantity Limit Overrides

Reference Number: PA.CP.PMN.59
Effective Date: 01/18
Last Review Date: 10/18

Coding Implications
Revision Log

Description
This policy establishes the criteria for overriding set quantity limits (QL).

FDA Approved Indication(s)
Varies by drug product.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness® that quantity limit (QL) edit exceptions are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Quantity Limit Exceptions (must meet all)**:**
Refer to Section IB for conditions eligible for continuity of care and Section IC for pain management

1. One of the following (a or b):
   a. Requested dose is supported by practice guidelines or peer-reviewed literature (e.g., phase 3 study or equivalent published in a reputable peer reviewed medical journal or text) for the relevant off-label* use and/or regimen (*prescriber must submit supporting evidence*);
   **Requests for off-label use must meet criteria outlined in the off-label use policy, PA.CP.PMN.53*
   b. Diagnosis of a condition/disease for which FDA dosing guidelines indicate a higher quantity (dose or frequency) than the currently set QL;
   Example: Proton pump inhibitors, which are commonly used for gastroesophageal reflux disease, have a QL of one dose per day; however, when there is a rare diagnosis such as Zollinger-Ellison syndrome, an override for two doses per day is allowed
2. Member has been titrated up from the lower dose with partial improvement without adverse reactions (dose optimization is required, refer to the dose-optimization policy, PA.CP.PMN.13).

Approval duration: 12 months

B. Continuity of care(must meet all)**:**
1. Refer to the Continuity of Care Policy (PA.LTSS.PHAR.01).

C. Narcotic Analgesics QL Exceptions
1. Refer to Long-Acting Narcotic Analgesics policy, PA.LTSS.PHARM.11
2. Refer to Short-Acting Narcotic Analgesics policy, PA.LTSS.PHARM.12

II. Continued Therapy:

A. All Requests in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized: Not Applicable

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
QL: quantity limit

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information
- Dose optimization is the consolidation of multiple units of lower strength to the fewest units required to achieve the desired daily dose/regimen based on commercially available dosage strengths. Requests for multiple units of a lower strength will be denied when the plan-approved QL for such medication is exceeded and higher strength units are commercially available to achieve the desired daily dose/regimen.

Request Example	Prescribed Regimen	Approvable Regimen
Request for Seroquel XR 800 mg/day	Seroquel XR 200 mg tablets, 4 tablets/day	Seroquel XR 400 mg tablets, 2 tablets/day
Request for aripiprazole 30 mg/day	Aripiprazole 15 mg tablets, 2 tablets/day	Aripiprazole 30 mg tablet, 1 tablet/day

V. Dosage and Administration
Not applicable

VI. Product Availability
Not applicable

VII. References
1. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain – United States, 2016. MMWR Recomm Rep. 2016; 65(1): 1-49.

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: converted to new template; combined criteria sets for rare conditions and off-label use to apply more broadly; added	08/18	

Reviews, Revisions, and Approvals	Date	Approval Date
oncology to list of possible continuation of care eligible conditions; referred off-label dosing to the off-label use policy; references reviewed and updated.		