Clinical Policy: Quantity Limit Override and Dose Optimization

Reference Number: PA.CP.PMN.59
Effective Date: 01/2018
Last Review Date: 10/2024

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

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 PA Health & Wellness ® that dose optimization is implemented when clinically appropriate. Prescribers are required to consolidate multiple units of lower strength to the fewest units required to achieve the desired daily dose/regimen based on commercially available dosage strengths (see *Appendix D* for examples). 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.

It is the policy of PA Health & Wellness® that quantity limit (QL) and dose optimization 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*);
   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. One of the following (a or b):
   a. Member has been titrated up from the lower dose with partial improvement without adverse reactions;
   b. For retail fill quantity limit, quantity limit requires multiple trips to the pharmacy in one month to complete therapy;
3. Dose optimization is required, unless one of the following applies (a or b):

a. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen.

Approval duration: 12 months (*60 days if dose optimization exception is requested due to dose titration*)

B. Continuity of care:

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy. Refer to the Continuity of Care Policy (PA.PHARM.01).

C. Narcotic Analgesics QL Exceptions

1. Refer to Long-Acting Opioid Analgesics policy, PHW.PDL.110
2. Refer to Short-Acting Opioid Analgesics policy, PHW.PDL.109

D. Dose Optimization Exceptions (must meet all)**:**

1. One of the following (a or b):
   a. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
   b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
2. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-recommended regimen and maximum daily dose;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Dose titration – Duration of request or 60 days, whichever is less
Other clinical reasons – Duration of request or 12 months, whichever is less

II. Continued Therapy:

A. All Requests in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Dose optimization is required, unless one of the following applies (a or b):
   a. Documentation supports the continued need for dose titration or tapering;
   b. Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
3. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-recommended regimen and maximum daily dose;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months (*60 days if dose optimization exception is requested due to dose titration*)

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. This can reduce pill burden, simplify therapeutic regimens, improve treatment compliance, and reduce pharmacy spend. 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
Varies by drug product

VI. Product Availability
Varies by drug product

VII. References
Not applicable

Reviews, Revisions, and Approvals	Date
4Q 2018 annual review: converted to new template; combined criteria sets for rare conditions and off-label use to apply more broadly; added oncology to list of possible continuation of care eligible conditions; referred off-label dosing to the off-label use policy; references reviewed and updated.	08/2018
09/01/2019 statewide PDL submission: Revised references to Long- and short-acting opioid policies to account for name change occurring with statewide PDL implementation 01/01/2020; removed reference to PA.CP.PMN.53	09/2019
4Q 2020 annual review: References reviewed and updated.	07/2020

Reviews, Revisions, and Approvals	Date
4Q 2021 annual review: no significant changes	10/2021
Added dose optimization criteria (PA.CP.PMN.13 retired).	07/2022
4Q 2022 annual review: no significant changes.	10/2022
Added retail fill limit override path	07/2023
4Q 2024 annual review: no significant changes.	10/2024