

Clinical Policy: Dose Optimization
Reference Number: PA.CP.PMN.13
Effective Date: 01/18
Last Review Date: 04/19
Line of Business: Medicaid

[Coding Implications](#)
[Revision Log](#)

Description

Dose optimization is a method to consolidate dosage units to the fewest units required to achieve the desired daily dose/regimen. This can reduce pill burden, simplify therapeutic regimens, improve treatment compliance, and reduce pharmacy spend.

FDA approved indication

N/A

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 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 B for examples). Requests for multiple units of a lower strength will be denied when the plan approved quantity limit for such medication is exceeded and higher strength units are commercially available to achieve the desired daily dose/regimen.

It is the policy of Pennsylvania Health and Wellness that exceptions to dose optimization are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Exceptions to Dose Optimization (must meet all):

1. Member meets one of the following (a,b, or c):
 - a. Dose titration: multiple lower strength units are requested for the purpose of dose titration;
 - b. Other clinical reasons: documented clinical rationale supports member inability to use the higher strength units to achieve the desired dose/regimen;
 - c. Dosing regimens supported by the compendia for labeled and off-labeled indications
2. Dose does not exceed FDA recommended regimen and maximum daily dose.
 - a. If request is for off-label utilization and the off-label policy is used to approve the request, the dosage approved will be consistent with the literature to support the off-label approval;
 - b. For QL exceptions, refer to PA.CP.PMN.59 – Quantity Limit Override.

Approval duration:

Dose titration: 60 days or duration of request, whichever is less

Other clinical reasons: 12 months or duration of request, whichever is less

II. Continued Therapy

A. Exceptions to Dose Optimization (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 meets one of the following (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. If request is for a dose increase, request meets one of the following (a, b, or c):
 - a. New dose does not exceed FDA recommended regimen and maximum daily dose unless compendia supports use of the requested dosing;
 - b. If request is for off-label utilization and the off-label policy is used to approve the request, the dosage approved will be consistent with the literature to support the off-label approval.
 - c. For QL exceptions, refer to PA.CP.PMN.59 – Quantity Limit Override.

Approval duration:

Dose titration: 60 days or duration of request, whichever is less

Other clinical reasons: 12 months or duration of request, whichever is less

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

A. N/A

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

N/A: not applicable

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindication/Boxed Warnings

Varies by drug product

Appendix D: Examples of Dose Optimization

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

CLINICAL POLICY

Dose Optimization



Varies by drug product

VII. References

1. N/A

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2019 annual review: added reference to PA.CP.PMN.59 Quantity Limit Override policy for QL exceptions.	04/19	