RXADVANCE
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Clinical Policy Title:	Quantity Limit Override
Policy Number:	RxA.256
Drug(s) Applied:	Quantity Limit Override
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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, b, or c):
   a. Requested dose is within the FDA approved maximum dose;
   b. 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, RxA.601*
   c. Diagnosis of a rare 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.

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. Continuity of Care (must meet all)**:**

1. State or health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, psychotic disorders [e.g., schizophrenia, bipolar disorder], and oncology);
2. Therapy will be titrated to the currently set QL (refer to the dose-optimization policy, RxA.77).

Approval duration
Commercial: 3 months, or 12 months if subject to state continuity of care program
Medicaid: 3 months, or 12 months if subject to state continuity of care program

II. Continued Therapy Approval

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

1. Currently receiving the requested quantity that has previously been authorized by RxAdvance or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose optimization is required (refer to the dose-optimization policy, RxA.77).

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym 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

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.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Criteria update: • I.A.1. Add “a. Requested dose is within the FDA approved maximum dose” as an option • Rephrase criteria II.A.1	04/30/2020	05/21/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated.	01/19/2021	03/09/2021

2. Line of Business Policy Applies to was update to all lines of business.		