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:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Quantity Limit Exceptions (must meet all)**:**

1. Refer to Section I.B for conditions eligible for continuity of care; 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. Member is currently receiving the requested quantity that has previously been authorized by RxAdvance or member has met initial approval criteria;
2. Member is responding positively to therapy;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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3. Dose optimization is required (refer to the dose-optimization policy, RxA.77).

Approval duration
Commercial: 12 months
Medicaid: 12 months

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. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. Accessed October 17, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Criteria update: 1. I.A.1. Add “a. Requested dose is within the FDA approved maximum dose” as an option 2. Rephrase criteria II.A.1	04/30/2020	05/21/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Line of Business Policy Applies to was update to all lines of business.	01/19/2021	03/09/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".	11/30/2021	01/17/2022
Policy was reviewed: 1. References were reviewed and updated.	10/17/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023

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