RxAdvance

Clinical Policy Title:	Quantity Limit Exception
Policy Number:	RxA.256
Drug(s) Applied:	Quantity Limit Exception
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
/ine of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Prescribed indication is FDA-approved or supported by one of the following (a or b):
   a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;
   b. Micromedex Drug Dex® with strength of recommendation Class I, IIa, or IIb;
2. Requested dose meets one of the following (a or b):
   a. Within the FDA-approved maximum dose;
   b. Supported by a compendia-supported dosing guideline (e.g. Micromedex, NCCN);
3. One of the following (a or b):
   a. The requested quantity is needed for dose titration;
   b. The requested dose cannot be achieved with a lower quantity of a higher strength that does not exceed the quantity limit.

Approval duration

All lines of business (except Medicare): The titration duration or 12 months.

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. The requested dose cannot be achieved with a lower quantity of a higher strength that does not exceed the quantity limit.

Approval duration

All lines of business (except Medicare): 12 months

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

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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
Policy was reviewed: 1. Removed continuity of care section. 2. Removed reauthorization requirement for positive response to therapy. 3. Removed titration criteria. 4. Added dose optimization criteria. 5. Added off-label sources. 6. Added dose optimization requirement for continued therapy.	12/05/2024	12/05/2024
Policy reviewed	12/11/2025	12/11/2025

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