RxAdvance

Clinical Policy Title:	Step Therapy Exception Criteria
Policy Number:	RxA.028
Drug(s) Applied:	This policy is limited to the requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria** (must meet all):
   1. The drugs must be prescribed for any medically accepted indications. Medically accepted indications are defined using the following compendia resources: The Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and Micromedex Information System with a Class I, IIa, or IIb strength of evidence. The reviewer may also reference disease state specific clinical practice guidelines published by a professional society or organization, with recommendations assigned Grading of Recommendations Assessment, Development and Evaluation (GRADE) system ratings of "Strong" based on "Moderate" or "High" quality evidence.
   2. Trial and failure of up to two (2) formulary agents within the same therapeutic class or formulary drugs that are recognized as standards of care for the treatment of the same diagnosis, each trialled for at least 30 days, unless all are contraindicated or clinically significant adverse effects are experienced. If only one FDA-approved drug exists, member only need to demonstrate failure of an adequate trial of that drug.
   3. Dose does not exceed FDA approved maximum recommended dose.

   Approval Duration
   Commercial: 12 months
   Medicaid: 12 months

II. **Continued Therapy Approval** (must meet all):
   1. Member is currently receiving medication that has been authorized by RxAdvance or the member has previously met initial approval criteria listed in this policy.
   2. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose.

   Approval Duration
   Commercial: 12 months
   Medicaid: 12 months

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was revised/reviewed.	02/2020	03/06/2020
Policy was reviewed. 1. Continued Therapy Approval criteria II.1 was rephrased to	05/2020	05/21/2020

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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"Currently receiving medication that has been authorized by RxAdvance…"		
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Added "If only one FDA-approved drug exists, member only need to demonstrate failure of an adequate trial of that drug" to criteria I.2.	1/26/2021	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...".	11/19/2021	01/17/2022
Policy was reviewed. 1. Initial Approval Criteria I.2: Updated from trial and failure of at least two (2) formulary agents to trial and failure of up to two (2) formulary agents.	09/28/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023

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