

Clinical Policy Title:	Formulary Exceptions
Policy Number:	RxA.137
Drug(s) Applied:	Multiple
Original Policy Date:	02/07/2020
Last Review Date:	03/23/2026
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Exceptions for Non-Formulary Drugs (must meet all):

See Section B for formulary exceptions for a brand name drug when a generic equivalent or biosimilar is available.

1. Diagnosis meets one of the following (a, b, or c):
 - a. Prescribed indication is FDA-approved;
 - b. Prescribed indication is supported by the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium with a level of evidence 1, 2A, or 2B;
 - c. Prescribed indication is supported by Micromedex Drug Dex® with strength of recommendation Class I, IIa, or IIb;
2. Trial and failure of at least two formulary alternatives within the same drug class that are FDA-approved for the same indication. If there is no such formulary alternative, trial and failure of two formulary drugs that are considered the standard of care unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of formulary agents is supported by one of the following (a or b):
 - a. Presence of paid pharmacy claims within the past 120 days;
 - b. Documentation in provider chart notes including medication name, strength, and dates of therapy;
4. If the request is for an opioid, member must additionally meet all criteria outlined in RxA.432 Opioid Analgesics;
5. Dosing meets one of the following (a or b):
 - a. Dose does not exceed the FDA-approved maximum recommended dose;
 - b. Dosing regimen is supported by compendia-supported guidelines;
6. For combination products, medical justification supports the inability to use the individual drug products;
7. If the request is for a drug outlined in the Hyperinflation Policy, additional requirements may be applied.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

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.

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met the initial approval criteria.

Approval duration

All lines of business (except Medicare): 12 months

References

Not applicable.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Approval duration was updated 2. Continue Therapy criteria II.A.1.a was rephrased to "Currently receiving medication that has been authorized by RxAdvance" 3. Initial Approval Criteria I.A.3.b was removed 	05/2020	05/21/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title table was updated. 2. Line of Business Policy Applies to was update from commercial to all lines of business. 3. Continued Therapy criteria II.A.1.b was rephrased to "Member has previously met initial approval criteria listed in this policy." 4. Added "If only one FDA-approved drug exists, member only need to demonstrate failure of an adequate trial of that drug" to criteria I.A.2, I.E.3 and I.F.2. 	01/19/2021	03/09/2021
Policy was reviewed.	11/26/2021	01/17/2022
Policy was reviewed <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.3.b: Updated to include new trial and failure criteria Documented contraindication(s) or clinically significant adverse effects to all formulary agents within the same therapeutic class or formulary drugs that are recognized as standards of care for the treatment of member's diagnosis. 2. Initial Approval Criteria, I.A.4: Updated to include new combination therapy criteria For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., 	10/14/2022	01/17/2023

<p>contraindications to the excipients of all alternative products);</p> <p>*Use of a copay card or discount card does not constitute medical necessity</p> <p>3. Initial Approval Criteria, 1.D.2: Updated trial and failure criteria from Trial and failure of an adequate trial of or clinically significant adverse effects to two generics* of the requested brand name drug, each from a different manufacturer, unless member has contraindications to the excipients in all generics to Trial and failure of an adequate trial of or clinically significant adverse effects to two generics* of the requested brand name drug, each from a different manufacturer, or the preferred biosimilar(s) unless member has contraindications to the excipients in all generics.</p> <p>4. Initial Approval Criteria, 1.E: Updated to remove approval criteria for Exceptions for combination products and alternative dosage forms or strengths of Existing Drugs.</p> <p>5. Initial Approval Criteria, 1.E.1: Updated to include new requesting criteria Request is for a formulary drug without custom coverage criteria;</p> <p>*All requests for non-formulary drugs, should be reviewed against Section I.A Exceptions for Non-Formulary or Tier 3 Drugs above</p> <p>6. Initial Approval Criteria, 1.E.2.a: Updated to remove prior diagnostic criteria "Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);".</p> <p>7. Initial Approval Criteria, 1.E.2.b: Updated to include new diagnostic criteria Diagnosis of one of the following (a or b):</p> <ol style="list-style-type: none"> a. Prescribed indication is FDA-approved; b. A condition supported by the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, or 2A. <p>8. Initial Approval Criteria, 1.E.4: Updated to include new combination therapy criteria For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or</p>		
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<p>alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products); *Use of a copay card or discount card does not constitute medical necessity.</p> <p>9. Initial Therapy Approval Criteria, I.E: Updated approval duration criteria for Exceptions for Drugs Requiring Prior Authorization without Custom Coverage Criteria from: Commercial: 6 months Medicaid: 6 months to Commercial: 12 months Medicaid: 12 months.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Added level of evidence 2B for Micromedex and NCCN. Removed Exceptions to Quantity Limit, Dose Optimization, and Drugs Requiring Prior Authorization without Custom Coverage Criteria. Removed dosing restrictions from the continued therapy criteria. Removed requirement for trial and failure of 2 formulary alternatives for drugs without custom coverage criteria. Add opioid requirements if applicable. Required trial and failure of 4 generics if the request is for a brand name drug. 	12/05/2024	12/05/2024
Policy reviewed	12/11/2025	12/11/2025
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Took out criteria for reviewing MSBs since these are not covered products. 	3/23/2026	3/26/2026