Clinical Policy Title:	Formulary Exceptions
Policy Number:	RxA.137
Drug(s) Applied:	Multiple
Original Policy Date:	02/07/2020
Last Review Date:	11/12/2024
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.

B. Exceptions for Non-Formulary Brand Name Drugs when a Generic Equivalent or Biosimilar is Available (must meet all):

1. Request is for a non-formulary brand name drug with a commercially available generic or biosimilar equivalent;
2. If the request is for a drug outlined in the Hyperinflation Policy, additional requirements may be applied;

3. Member meets one of the following (a or b):
   a. Adequate trial and failure of at least four generics of the requested brand name drug, each from a different manufacturer, unless member has contraindications to the excipients in all generics;
   b. Trial and failure of all formulary biosimilars of the requested brand name drug, unless member has contraindications to the excipients in all biosimilars.

   *If additional generics of the requested brand name drug are not available, member must try up to 4 formulary alternatives that are FDA-approved or supported by standard pharmacopeias (e.g., Micromedex) for the requested indication.
4. If the request is for an opioid, member must additionally meet all criteria outlined in RxA.432 Opioid Analgesics.

Approval duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

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: 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: 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 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., contraindications to the excipients of all alternative products); *Use of a copay card or discount card does not constitute medical necessity 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. 4. Initial Approval Criteria, I.E: Updated to remove approval criteria for Exceptions for combination products and alternative dosage forms or strengths of Exisiting Drugs. 5. Initial Approval Criteria, 1.E.1: Updated to include new requesting criteria Request is for a formulary drug without custom coverage criteria; *All requests for non-formulary drugs, should be reviewed against Section I.A Exceptions for Non-Formulary or Tier 3 Drugs above 6. Initial Approval Criteria, I.E.2.a: Updated to remove prior diagnostic criteria "Prescribed	10/14/2022	01/17/2023

indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);". 7. Initial Approval Criteria, I.E.2.b: Updated to include new diagnostic criteria Diagnosis of one of the following (a or b): 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. 8. Initial Approval Criteria, I.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 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. 9. Initial Therapy Approval Crtieria, 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.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Added level of evidence 2B for Micromedex and NCCN. 2. Removed Exceptions to Quantity Limit, Dose Optimization, and Drugs Requiring Prior Authorization without Custom Coverage Criteria. 3. Removed dosing restrictions from the continued therapy criteria. 4. Removed requirement for trial and failure of 2 formulary alternatives for drugs without custom coverage criteria. 5. Add opioid requirements if applicable. 6. Required trial and failure of 4 generics if the request is for a brand name drug.	12/05/2024	12/05/2024