Clinical Policy Title:	Formulary Exceptions
Policy Number:	RxA.137
Drug(s) Applied:	Multiple
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. Exceptions for Non-Formulary or Tier 3 Drugs (must meet all):

Not applicable to formulary exceptions for a brand name drug when a generic drug equivalent is available; Tier 3 exceptions apply to plans where prior authorization is required for all Tier 3 drugs.

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g. Micromedex);
2. Trial and failure of at least two formulary alternatives within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such alternatives exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment (If only one FDA-approved drug exists, member only need to demonstrate failure of an adequate trial of that drug);
3. Trial and failure of formulary agents is supported by one of the following (a, b, c or d):
   a. Presence of claims in pharmacy claims history;
   b. 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;
   c. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
   d. Documentation in provider chart notes which include all of the following: medication name, dose/strength, and start/end dates of therapy;
4. 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
5. Request meets one of the following (a or b):*
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration

Commercial: 12 months

Medicaid: 12 months

B. Exceptions to Quantity Limit (must meet all)**:**

1. One of the following (a, b, c, d, or e):
   a. 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) and member has been titrated up from the lower dose with partial improvement without adverse reactions (dose optimization is required, refer to the dose-optimization criteria in Section IC below); *Requests for off-label use must meet criteria outlined in the off-label use policy, RxA.601;
   b. Diagnosis of a rare condition/disease* for which FDA dosing guidelines indicate a higher quantity (dose or frequency) than the currently set quantity limit (QL) and member has been titrated up from the lower dose with partial improvement without adverse reactions (dose optimization is required);
   *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.
   c. Request is for a condition eligible for continuity of care (e.g., seizures, heart failure, human immunodeficiency virus infection, psychotic disorders [e.g., schizophrenia, bipolar disorder], and oncology), and therapy will be titrated to be within the currently set QL;
   d. Request is for pain management in cancer, sickle cell anemia, palliative care, or end-of-life care;
   e. Request is for pain management and both of the following (i and ii):
      i. Member has a signed treatment plan specific to his/her care with a single qualified prescriber;
      ii. Prescriber has provided his/her plan of action (which may include historical titration schedule to the current dose and/or titration schedule to decrease the dose to be within the currently set QL;
2. Trial and failure of preferred alternatives prior to dose escalation may be required if medically appropriate.

Approval duration
Pain management in cancer, sickle cell anemia, palliative care, or end-of-life care: 12 months
All other indications: 6 months

C. Exceptions to Dose Optimization (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
   b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
2. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-recommended regimen and maximum daily dose;
   b. For QL exceptions, refer to Section I.B above.

Approval duration:
Dose titration: 3 months
Other clinical reasons: 12 months

D. Exceptions for Brand Name Drug When a Generic Equivalent is Available (must meet all):

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., Micromedex);
2. 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;
*If a second generic of the requested brand name drug is not available, member must try a formulary alternative that is FDA-approved or supported by standard pharmacopeias (e.g., Micromedex) for the requested indication, provided that such agent exists

3. Provider submits clinical rationale* supporting why the brand name drug will be more effective than the generic or will not produce the same adverse effects as the generic;
*Use of a copay card or discount card does not constitute medical necessity
4. Request meets one of the following (a or b):*
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 12 months

E. Exceptions for Drugs Requiring Prior Authorization without Custom Coverage Criteria (must meet all)**:**

1. 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
2. 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;
3. Trial and failure of at least two formulary alternatives within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such alternatives exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment unless contraindicated or clinically significant side effects are experienced (If only one FDA-approved drug exists, member only need to demonstrate failure of an adequate trial of that drug);
4. 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
5. Request meets one of the following (a or b):*
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy

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

1. One of the following (a, b, or c):
   a. Member is currently receiving medication that has been authorized by RxAdvance;
   b. Member has previously met initial approval criteria listed in this policy;
   c. 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) with documentation that supports that member has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For QL exception requests for dose titrations, one of the following (a or b):
   a. Documentation supports the continued need for dose titration or medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
   b. Medical justification supports continued need for quantities above the QL;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:
QL exceptions for continued dose titrations: 3 months
All other indications: 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: • Approval duration was updated • Continue Therapy criteria II.A.1.a was rephrased to “Currently receiving medication that has been authorized by RxAdvance” • 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