Clinical Policy: Formulary Exceptions

Reference Number: ERX.PA.02
Effective Date: 06.01.18
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
This policy applies to requests for formulary exceptions.

FDA Approved Indication(s)
Varies by drug product.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that formulary exceptions are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. 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., DrugDex);
2. Failure of an adequate trial of or clinically significant adverse effects to two generics* (each from a different manufacturer) or the preferred biosimilar(s) of the requested brand name drug, unless member has contraindications to the excipients in all generics/biosimilars;
   **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., DrugDex) 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*).

Approval duration:
Commercial – Length of Benefit
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);

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, refer to the dose-optimization criteria in Section IC below);
**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, and psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology), and therapy will be titrated to be within the currently set QL (refer to the dose-optimization criteria in Section IC below);
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 [refer to the dose-optimization criteria in Section IC below]);

2. Failure of preferred alternatives prior to dose escalation may be required if medically appropriate.

Approval duration:
Commercial –
Pain management in cancer, sickle cell anemia, palliative care, end of life care – Length of Benefit
All other indications – 3 months
Medicaid –
Condition eligible for continuity of care – 3 months, or 12 months if subject to state continuity of care program
Pain management NOT in cancer, sickle cell anemia, palliative care, end of life care – 3 months
All other indications – 12 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 IB above.

Approval duration:
Dose titration –
Commercial – 3 months
Medicaid – Duration of request or 60 days, whichever is less
Other clinical reasons –
Commercial – Length of Benefit
Medicaid – Duration of request or 12 months, whichever is less

II. Continued Therapy
A. All Exceptions in Section I (must meet all)**:**
1. One of the following (a, b, or c):
   a. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions;

b. Member has previously met initial approval criteria;
c. Health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, and psychotic disorders [e.g., schizophrenia, bipolar disorder], 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*).

Approval duration:
QL exceptions for continued dose titrations –
Commercial – 3 months
Medicaid – Duration of request or 60 days, whichever is less
All other indications –
Commercial – Length of Benefit
Medicaid – Duration of request or 12 months, whichever is less

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
QL: quantity limit

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

- A generic drug is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic substitution is mandatory when A-rated generic equivalents are available; however, brand name drugs may be approved in certain circumstances where there are adverse reactions to or therapeutic failure of generic drugs. Examples of failure of a generic drug include:
  - Suboptimal drug plasma levels while taking the generic drug as compared to drug plasma levels while taking the brand name drug;
  - Increase or worsening in symptoms (e.g., increase in seizure activity) when switched to a generic drug that is not attributed to progression of the disease state, increase in member age or weight, or member non-compliance.
- Dose optimization is the consolidation of multiple units of lower strength to the fewest units required to achieve the desired daily dose/regimen based on commercially available dosage strengths. Requests for multiple units of a lower strength will be denied when the plan-approved QL for such medication is exceeded and higher strength units are commercially available to achieve the desired daily dose/regimen.

Request Example	Prescribed Regimen	Approvable Regimen
Request for Seroquel XR 800 mg/day	Seroquel XR 200 mg tablets, 4 tablets/day	Seroquel XR 400 mg tablets, 2 tablets/day

Request Example	Prescribed Regimen	Approvable Regimen
Request for aripiprazole 30 mg/day	Aripiprazole 15 mg tablets, 2 tablets/day	Aripiprazole 30 mg tablet, 1 tablet/day

V. Dosage and Administration
Varies by drug product

VI. Product Availability
Varies by drug product

VII. References
Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.01.18	05.18
4Q 2018 annual review: modified policy name from Dose Optimization to Formulary Exceptions; added formulary exceptions for brand name drugs with available generic alternative and QL; added continuation of care language to section II.	08.14.18	11.18
4Q 2019 annual review: no significant changes; added Medicaid line of business with Medicaid-specific approval durations; references reviewed and updated.	08.12.19	11.19
4Q 2020 annual review: for I.A Exceptions for Brand Name Drug When a Generic Equivalent is Available, added redirection to biosimilars; for I.B Exceptions to Quantity Limit, removed cross reference to the off-label use policy per PA Ops request; references reviewed and updated.	07.13.20	11.20
4Q 2021 annual review: no significant changes.	07.22.21	11.21
4Q 2022 annual review: no significant changes.	08.02.22	11.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.