Clinical Policy: Request for Medically Necessary Drug Not on the PDL

Reference Number: ERX.PA.03
Effective Date: 12.01.18
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

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

Description
The intent of the criteria is to ensure that members follow selection elements established by Envolve Pharmacy Solutions for drugs that are not on the preferred drug list (PDL).

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 non-PDL drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for a Non-PDL Drug (must meet all)**:**

1. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against ERX.PA.01 – Global Medical Necessity, Section IB*
2. Failure of at least two PDL agents 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 agents 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 clinically significant adverse effects are experienced or all are contraindicated;
3. Trial and failure of PDL agents is supported by one of the following (a, b, c, or d):
   a. Presence of claims in pharmacy claims history supporting failure of preferred agents as described in criteria 2 above;
   b. Documented contraindication(s) or clinically significant adverse effects to ALL PDL agents within the same therapeutic class or PDL 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 and health plan approved daily quantity limit;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 12 months (whichever is less)

II. Continued Therapy

A. Request for a Non-PDL Drug (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. 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 and health plan approved daily quantity limit;
   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: 12 months

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
PDL: preferred drug list

Appendix B: Therapeutic Alternatives
Varies by drug product.

Appendix C: Contraindications/Boxed Warnings
Varies by drug product.

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.	08.14.18	11.18
4Q 2019 annual review: added that trial and failure of PDL agents can also be supported by chart notes; references reviewed and updated.	08.27.19	11.19
4Q 2020 annual review: no significant changes; added bypass of required PDL agent trials if clinically significant adverse effects are experienced or all are contraindicated; clarified claims history for non-PDL drug requests must support requirements for failure of preferred agents; references reviewed and updated.	07.13.20	11.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes; added clarification and reference to off-label use policy.	07.22.21	11.21

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.