Clinical Policy: Compounded Medications

Reference Number: ERX.PA.04
Effective Date: 12.01.19
Last Review Date: 08.22
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 compounded medications.

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 compounded medications are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All FDA-Approved Indications (must meet all)**:**

1. Compound ingredients are FDA-approved;
2. One of the following (a or b):
   a. Medical justification supports inability to use commercially available FDA-approved products (e.g., allergy to a certain dye and need for a medication to be made without it, elderly patient who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form);
   b. Prescribed for pediatric dosing in the absence of commercially available products;
3. Acceptable compendium supports efficacy and safety for the indicated treatment (*see Appendix D);*
4. Prescribed dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 1 month

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All FDA-Approved Indications (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the relevant indication.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: Acceptable Compendia
- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Truven Health Analytics Micromedex DrugDEX (DrugDEX), with strength of recommendation Class I or IIa
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, level of evidence 1, 2A, or 2B
- Elsevier/Gold Standard Clinical Pharmacology

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	08.21.19	11.19
Added examples of medical justification; refined medical literature to be a specific compendium with addition of Appendix D; revised initial approval duration to 1 month and continued approval duration to 6 months.	05.20.20	08.20
4Q 2020 annual review: no significant changes.	08.08.20	11.20
4Q 2021 annual review: allowed NCCN 2B as acceptable compendia and evidence rating in Appendix D.	07.15.21	11.21
3Q 2022 annual review: no significant changes.	05.17.22	08.22

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.