Clinical Policy: Compounded Prescriptions

Reference Number: PHW.PDL.00
Effective Date: 06/2022
Last Review Date: 07/2025

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.

It is the policy of health plans affiliated with PA Health and Wellness® that Compounded Prescriptions is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Compounded Prescriptions

A. Prescriptions That Require Prior Authorization

All compounded prescriptions must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a compounded prescription, determination of whether the requested prescription is medically necessary will take into account:

1. Compound ingredients are FDA-approved, if request is for compounded IV antibiotic please use PA.CP.PHAR.15 (Injectable Antibiotics Not on the Statewide Preferred Drug List);
2. Treatment is not for a benefit-excluded purpose (e.g., cosmetic, fertility enhancement, erectile disfunction , etc);
3. One of the following (a, b or c):
   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;
   c. Prescribed in the place of an FDA-approved product that is in shortage per the FDA or ASHP Drug Shortages list (*see Appendix E*)
4. Acceptable compendium or peer-reviewed literature supports efficacy and safety for the indicated treatment and route of administration;
5. Prescribed dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 6 months

Prescribed for FDA-approved product in shortage – up to anticipated resolution date or 3 months for unknown resolution date

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF COMPOUNDED PRESCRIPTION: The determination of medical necessity of a request for prior authorization of a renewal of a compounded prescription that was previously approved will take into account whether:

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
2. Treatment is not for a benefit-excluded purpose (e.g., cosmetic, fertility enhancement, erectile disfunction , etc);
3. Member is responding positively to therapy;
4. For FDA-approved product in drug shortage, drug is still in shortage per the FDA or ASHP Drug Shortages list (*see Appendix E*);
5. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 12 months

Prescribed for FDA-approved product in shortage – up to anticipated resolution date or 6 months for unknown resolution date

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

I. 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

Appendix E: Drug Shortage Resources

- The FDA's Drug Shortages Index can be found at: https://dps.fda.gov/drugshortages
- ASHP's Drug Shortages List can be found at: https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list

II. Dosage and Administration

Varies by drug product

III. Product Availability

Varies by drug product

D. References

1. Ensuring Safety of Compounded Preparations. The Pharmacists Letter, December 2012.
2. Miller, DG. (October 2013). Pharmacy Compounding Law and Regulations. Presentation at the Eastern Medicaid Pharmacy Administrators Association Annual Meeting, Ellicott City, MD. 3. Gudeman J., Jozwiakowski M., Chollet J., Randell M.; Potential Risks of Pharmacy Compounding. Drugs R D (2013) 13:1-8
4. Rood JM, Engels MJ, Ciarkowski SL, Wagenknecht LD, Dickinson CJ, Stevenson JG. Variability in Compounding of Oral Liquids for Pediatric Patients: A Patient Safety Concern. Am Pharm Assoc. 2014;54(4):383-389.
5. United States Food and Drug Administration. Compounding and the FDA: Questions and Answers. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#approved
6. Walls AP, Johnson S, Nguyen M. O'Lenic K, Pokorney T, Randolph s. Compounding is Confounding Workers' Compensation. 2014 CompPharma.

Reviews, Revisions, and Approvals	Date
Policy created	06/2022
3Q 2023 annual review: updated wording	07/2023
Include criteria to excluded benefit exclusions	01/2024
3Q 2024 annual review: no significant changes.	07/2024
3Q 2025 annual review: For initial therapy, added criteria option that compounded drug is prescribed in the place of an FDA-approved product that is in shortage per the FDA or ASHP Drug Shortages list and respective approval duration as "up to anticipated resolution date or 3 months for unknown resolution date;" for continued therapy for FDA-approved product in shortage,	07/2025

Reviews, Revisions, and Approvals	Date
added requirement that product is still in shortage and approval duration as "up to anticipated resolution date or 6 months for unknown resolution date."Added route of administration, in addition to the indication, for requirement that acceptable compendium supports efficacy and safety.	