Clinical Policy: Compounded Prescriptions

Reference Number: PHW.PDL.00
Effective Date: 06/2022
Last Review Date: 07/2023

Revision Log

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. 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 or peer-reviewed literature supports efficacy and safety for the indicated treatment;
4. Prescribed dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.
   Approval duration: 6 months

NOTE: If the beneficiary 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 beneficiary, 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.LTSS.PHAR.01) applies.
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: 12 months

NOTE: If the beneficiary 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 beneficiary, 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.

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