


ISSUE DATE June 29, 2023	EFFECTIVE DATE July 10, 2023	NUMBER *See below
SUBJECT Prior Authorization of Compounded Prescriptions – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Compounded Prescriptions submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Compounded Prescriptions to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Compounded Prescriptions to revise the language in the guidelines for clarity and consistency. There are no other changes to the medical necessity guidelines.

*01-23-15	09-23-15	27-23-09	33-23-15
02-23-08	11-23-08	30-23-12	
03-23-08	14-23-08	31-23-16	
08-23-19	24-23-14	32-23-08	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The revisions to the guidelines to determine medical necessity of prescriptions for Compounded Prescriptions were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Compounded Prescriptions are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Compounded Prescriptions) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 compounded prescription, the determination of whether the requested prescription is medically necessary will take into account:

1. The clinical rationale for using a compounded product in place of a U.S. Food and Drug Administration-approved product; **AND**
2. Peer reviewed medical literature supporting use of the compounded product for the beneficiary's indication.

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 PRIOR AUTHORIZATION FOR COMPOUNDED PRESCRIPTIONS:
The determination of medical necessity of a request for renewal of a prior authorization for a compounded prescription that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication.

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 a compounded prescription. 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 beneficiary.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

D. Dose and Duration of Therapy

Requests for prior authorization of compounded prescriptions will be approved as follows:

1. Initial requests for prior authorization of a compounded prescription will be approved for up to 6 months.
2. Renewals of requests for prior authorization of a compounded prescription will be approved for up to 12 months.

E. 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.