


ISSUE DATE June 29, 2023	EFFECTIVE DATE July 10, 2023	NUMBER *See below
SUBJECT Prior Authorization of Cough and Cold Medications – 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 Cough and Cold Medications 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 Cough and Cold Medications to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and

*01-23-16	09-23-16	27-23-10	33-23-16
02-23-09	11-23-09	30-23-13	
03-23-09	14-23-09	31-23-17	
08-23-20	24-23-15	32-23-09	

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 Web site at
<https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the April 26, 2023, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Cough and Cold Medications:

- Clarification that the requirement for prior authorization of a Cough and Cold Medication that contains an opioid when prescribed for a child applies to beneficiaries 6 to 17 years of age.
- Addition of a requirement for prior authorization of a Cough and Cold Medication that contains an opioid when a beneficiary has a concurrent prescription for a buprenorphine agent with a U.S. Food and Drug Administration (FDA)-approved indication for opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol) and corresponding guidelines to determine medical necessity.
- Addition of a requirement for prior authorization of a Cough and Cold Medication with a prescribed quantity that exceeds the quantity limit, which is subject to the guidelines in the Quantity Limits Chapter.
- Addition of a guideline that the beneficiary is prescribed a dose that is appropriate based on the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- Revision to the language for prior authorization of a Cough and Cold Medication for a beneficiary under 18 years of age to remove the list of alternative treatment examples and include therapeutic failure of or a contraindication or an intolerance to alternative treatments medically accepted for the beneficiary's diagnosis.
- In response to health and safety concerns discussed by the DUR Board and consistent with guidance by the FDA and American Academy of Pediatrics, addition of a guideline for a Cough and Cold Medication for a beneficiary under 18 years of age that the beneficiary is not prescribed a Cough and Cold Medication that contains an opioid.
- Addition of guidelines for a Cough and Cold Medication that contains promethazine for a beneficiary under 6 years of age based on the FDA black box warnings for promethazine.
- Clarification that, in response to health and safety concerns, the Department will not cover a 5-day supply of a Cough and Cold medication that contains an opioid for a beneficiary under 18 years of age.

The revisions to the guidelines to determine medical necessity of prescriptions for Cough and Cold Medications submitted for prior authorization, as recommended by the DUR Board, 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 Cough and Cold Medications 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 Cough and Cold Medications) 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>

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PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Cough and Cold Medications

A. Prescriptions That Require Prior Authorization

Prescriptions for Cough and Cold Medications that meet any of the following conditions must be prior authorized:

1. A Cough and Cold Medication when prescribed for a beneficiary under 6 years of age.
2. A Cough and Cold Medication that contains an opioid when prescribed for a beneficiary 6 to 17 years of age.
3. A Cough and Cold Medication that contains an opioid when a beneficiary has a concurrent prescription for a buprenorphine agent with a U.S. Food and Drug Administration (FDA)-approved indication for opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol).
4. A Cough and Cold Medication with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Cough and Cold Medication, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed a dose that is appropriate based on the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. For a Cough and Cold Medication prescribed for a beneficiary under 18 years of age, **all** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to alternative treatments medically accepted for the beneficiary's diagnosis,
 - b. Has a chart documented evaluation for other diagnoses, such as allergies, bronchitis, pneumonia, etc., if symptoms last longer than one week,
 - c. Is not prescribed a Cough and Cold Medication that contains an opioid;

AND

3. For a Cough and Cold Medication that contains promethazine for a beneficiary under 6 years of age, **both** of the following:
 - a. Will not be taking concomitantly with a medication with respiratory depressant effects
 - b. Does not have a history of a contraindication to the prescribed medication;

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AND

4. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), **both** of the following:
 - a. Is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to alternative treatments, including non-opioid Cough and Cold Medications, medically accepted for the beneficiary's diagnosis;

AND

5. If a prescription for a Cough and Cold Medication is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

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 prescription for a Cough and Cold Medication. 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.

D. 5-Day Supply

In response to health and safety concerns, the Department of Human Services will not cover a 5-day supply of a Cough and Cold Medication for a beneficiary under 6 years of age or a Cough and Cold Medication that contains an opioid for a beneficiary under 18 years of age.

E. References

1. US Food and Drug Administration. Prescription opioid cough and cold medicines: Drug safety communication -- FDA requires labeling changes. January 2018. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-requires-labeling-changes-prescription-opioid-cough-and-cold>. (Accessed on March 29, 2023).

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2. Hampton T. Promethazine Warning. JAMA. 2005;293(8):921.
3. Hycodan [package insert]. Allentown, PA. Genus Lifesciences Inc. September 2021.
4. Promethazine HCl and Codeine Phosphate [package insert]. Baudette, MN. ANI Pharmaceuticals, Inc. June 2018.