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 Analgesics, Non-Opioid Barbiturate Combinations submitted for prior authorization.

SCOPE: This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Analgesics, Non-Opioid Barbiturate Combinations will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Analgesics, Non-Opioid Barbiturate Combinations to the appropriate managed care organization.

01-20-11 09-20-10 27-20-06 33-20-07
02-20-04 11-20-04 30-20-03
03-20-04 14-20-05 31-20-11
08-20-14 24-20-05 32-20-03

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.
BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Analgesics, Non-Opioid Barbiturate Combinations to remove carisoprodol from the list of drugs specified in the urine drug screen guideline and to update the formatting of the guideline. There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of Analgesics, Non-Opioid Barbiturate Combinations 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 Analgesics, Non-Opioid Barbiturate Combinations 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 Analgesics, Non-Opioid Barbiturate Combinations) 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 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
I. Requirements for Prior Authorization of Analgesics, Non-Opioid Barbiturate Combinations

A. Prescriptions That Require Prior Authorization

All prescriptions for Analgesics, Non-Opioid Barbiturate Combinations must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of an Analgesic, Non-Opioid Barbiturate Combination, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Analgesic, Non-Opioid Barbiturate Combination for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. If age 65 years or older, **both** of the following:
   a. Received a risk assessment by the prescriber and the prescriber indicated that the benefits of the requested medication outweigh the risks for the beneficiary
   b. Has documentation of prescriber counseling regarding the potential increased risks of the requested medication;
   **AND**

4. Is not taking primidone or other medication(s) containing a barbiturate; **AND**

5. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

6. Will not be taking the requested medication on more than three (3) days per month; **AND**

7. Has a diagnosis of headache based on the current International Headache Society Classification of Headache Disorders; **AND**

8. Has a history of trial and failure, intolerance, or contraindication of standard abortive medication based on headache classification as recommended by the most recent American Academy of Neurology, American Academy of Family Physicians, World Health Organization, or European Academy of Neurology treatment guidelines; **AND**
9. If being treated for chronic daily headache, defined as the presence of headache on 15 days or more per month for at least three (3) months, **all** of the following:

   a. Has documentation of results of a physical examination and complete neurologic examination to rule out secondary causes of headache,

   b. Has documentation of an evaluation for the overuse of abortive medications, including but not limited to acetaminophen, NSAIDs, triptans, butalbital, caffeine, and opioids,

   c. Has documentation of prescriber counseling regarding behavioral modifications, such as cessation of caffeine and tobacco use, improved sleep hygiene, diet changes, and regular mealtimes,

   d. **One** of the following:

      i. Is taking preventive drug therapy based on headache classification as recommended by the most recent American Academy of Neurology, American Academy of Family Physicians, World Health Organization, or European Academy of Neurology treatment guidelines

      ii. Has a contraindication or intolerance of standard preventive drug therapies,

   e. Has documentation of prescriber counseling regarding the potential adverse effects of Analgesics, Non-Opioid Barbiturate Combinations, including the risk of medication overuse headache, misuse, abuse, and addiction,

   f. For a beneficiary with a history of substance use disorder, has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances;

**AND**

10. Is being treated by a prescribing provider who confirms that he/she, or the prescribing provider’s delegate, conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history before prescribing the Analgesic, Non-Opioid Barbiturate Combination; **AND**

11. For a non-preferred Analgesic, Non-Opioid Barbiturate Combination, has a history of therapeutic failure, contraindication, or intolerance of the preferred Analgesic, Non-Opioid Barbiturate Combinations. See the Preferred Drug List (PDL) for the list of preferred Analgesics, Non-Opioid Barbiturate Combinations at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

12. If a prescription for an Analgesic, Non-Opioid Barbiturate Combination 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. 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.

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 an Analgesic, Non-Opioid Barbiturate Combination. 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

The Department of Human Services will cover a 5-day supply of the prescribed medication without prior authorization if, in the professional judgment of the dispensing pharmacist, the beneficiary has an immediate need for the medication, unless the dispensing pharmacist determines that taking the medication either alone or along with other medications that the beneficiary may be taking would jeopardize the health and safety of the beneficiary. The maximum number of 5-day supplies of a prescription for an Analgesic, Non-Opioid Barbiturate Combination that the Department will cover without prior authorization is one 5-day supply per beneficiary during a 6-month period.