


<b>ISSUE DATE</b>  September 10, 2019	<b>EFFECTIVE DATE</b>  January 1, 2020	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Sedative Hypnotics – Pharmacy Services		<b>BY</b>   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: [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**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 Sedative Hypnotics 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 Sedative Hypnotics to the appropriate managed care organization.

**BACKGROUND/DISCUSSION:**

The Department of Human Services (Department) is updating the medical necessity guidelines for Sedative Hypnotics to change “Suboxone and Subutex” to “a buprenorphine agent indicated for the treatment of opioid use disorder” to include all buprenorphine products

*01-19-55	09-19-51	27-19-49	
02-19-49	11-19-48	30-19-47	
03-19-48	14-19-47	31-19-54	
08-19-57	24-19-49	32-19-47	33-19-51

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  
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

on the market with this indication and exclude the buprenorphine agents approved only for the treatment of pain. There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of Sedative Hypnotics 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 Sedative Hypnotics 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 Sedative Hypnotics) 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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

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

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Sedative Hypnotics**

**A. Prescriptions That Require Prior Authorization**

Prescriptions for Sedative Hypnotics that meet any of the following conditions must be prior authorized:

1. A non-preferred Sedative Hypnotic. See the Preferred Drug List (PDL) for the list of preferred Sedative Hypnotics at: <https://papdl.com/preferred-drug-list>.
2. A Sedative Hypnotic benzodiazepine when prescribed for a child under 21 years of age.
3. A Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance) when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.
4. A Sedative Hypnotic 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: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

**B. Review of Documentation for Medical Necessity**

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

1. For a non-preferred Sedative Hypnotic, has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Sedative Hypnotics approved or medically accepted for the beneficiary's diagnosis or indication; **AND**
2. For a non-preferred controlled-release Sedative Hypnotic, has a documented history of therapeutic failure of the same regular-release Sedative Hypnotic; **AND**
3. For a Sedative Hypnotic benzodiazepine for a child under 21 years of age, **one** of the following:
  - a. Has a diagnosis of **one** of the following:
    - i. Seizure disorder,
    - ii. Chemotherapy induced nausea and vomiting,
    - iii. Cerebral palsy,
    - iv. Spastic disorder,
    - v. Dystonia
  - b. Is receiving palliative care;

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**AND**

4. For Hetlioz (tasimelteon), **all** of the following:
  - a. Has a diagnosis of non-24 hour sleep-wake disorder,
  - b. Is totally blind (has no light perception),
  - c. **One** of the following:
    - i. Has a documented history of therapeutic failure of a 6-month trial of melatonin
    - ii. Has documented contraindication or intolerance to melatonin;

**AND**

5. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:
  - a. Is prescribed the buprenorphine agent and the Sedative Hypnotic controlled substance by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
  - b. Has an acute need for therapy with the Sedative Hypnotic controlled substance;

**AND**

6. For a Sedative Hypnotic controlled substance, has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history; **AND**
7. If a prescription for a Sedative Hypnotic 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 above but, in the professional judgement 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 SEDATIVE HYPNOTICS: The determination of medical necessity of a request for renewal of a prior authorization for a Sedative Hypnotic that was previously approved will take into account whether the beneficiary:

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

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2. For a Sedative Hypnotic controlled substance, has documentation that the prescriber or the prescriber's delegate conducted a search of the PDMP for the beneficiary's controlled substance prescription history; **AND**
3. If the prescription for a Sedative Hypnotic 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 above but, in the professional judgement 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 Sedative Hypnotic. 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. Automated Prior Authorization

Prior authorization of a prescription for a preferred Sedative Hypnotic benzodiazepine for a child under 21 years of age will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 180 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.