

ISSUE DATE November 13, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below
SUBJECT Prior Authorization of Sedative Hypnotics – 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 Sedative Hypnotics 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 Sedative Hypnotics 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 Sedative Hypnotics to the appropriate managed care organization.

*01-20-41	09-20-40	27-20-36	33-20-37
02-20-34	11-20-34	30-20-33	
03-20-34	14-20-35	31-20-41	
08-20-44	24-20-34	32-20-33	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type.</p> <p>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.</p>

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the August 12, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Sedative Hypnotics:

- Addition of the following to Prescriptions That Require Prior Authorization and corresponding guidelines to determine medical necessity:
 - A prescription for a Sedative Hypnotic benzodiazepine when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations] in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication) and
 - A prescription for a Sedative Hypnotic benzodiazepine when there is a record of two or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days; and
- Clarification that the guidelines specific to Hetlioz (tasimelteon) apply to requests for a Sedative Hypnotic for the treatment of non-24-hour sleep-wake disorder;
- Addition of a guideline that treatment of the beneficiary's diagnosis with the requested non-preferred Sedative Hypnotic is consistent with U.S. Food and Drug Administration-approved package labeling or medical literature;
- Revision to the guideline related to the Prescription Drug Monitoring Program (PDMP) for a beneficiary with a diagnosis of seizure disorder, chemotherapy-induced nausea and vomiting, cerebral palsy, spastic disorder, or dystonia; and
- Addition of guidelines for renewal requests for a Sedative Hypnotic benzodiazepine for a beneficiary under 21 years of age.

The revisions to the guidelines to determine medical necessity of Sedative Hypnotics, as recommended by the P&T Committee, 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

<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 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 beneficiary under 21 years of age.
3. A Sedative Hypnotic benzodiazepine when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. A Sedative Hypnotic benzodiazepine when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days.
5. 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.
6. 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: <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 Sedative Hypnotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a Sedative Hypnotic benzodiazepine for a beneficiary 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,

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- iv. Spastic disorder,
- v. Dystonia

b. Is receiving palliative care;

AND

2. For a diagnosis of non-24-hour sleep-wake disorder, **both** of the following:
 - a. Is totally blind (has no light perception)
 - b. **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

3. For a non-preferred Sedative Hypnotic, **both** of the following:
 - a. Is prescribed the Sedative Hypnotic for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication
 - b. 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

4. For a non-preferred controlled-release Sedative Hypnotic, has a documented history of therapeutic failure of the same regular-release Sedative Hypnotic; **AND**
5. For therapeutic duplication of a benzodiazepine, **one** of the following:
 - a. Is being titrated to or tapered from another benzodiazepine
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

6. When there is a record of 2 or more paid claims for any benzodiazepine, **both** of the following:
 - a. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed literature or national treatment guidelines

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- b. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s);

AND

- 7. 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

- 8. For a Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), **one** of the following:
 - a. Meets the guidelines in B.1.
 - b. 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

- 9. 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. For a Sedative Hypnotic benzodiazepine for a beneficiary 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,

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- iv. Spastic disorder,
- v. Dystonia

b. Is receiving palliative care;

AND

- 2. Has documentation of tolerability and a positive clinical response to the medication; **AND**
- 3. For a Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), **one** of the following:
 - a. Meets the guidelines in RENEWAL B.1.
 - b. 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

- 4. 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 beneficiary under 21 years of age will be automatically approved when the Point-of-Sale Online 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.