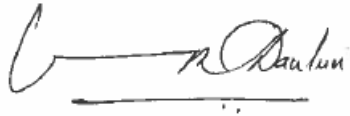


Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	Submission Date: N/A
Policy Number: PHW.PDL.054	Effective Date: 01/01/2020 Revision Date: 10/2021
Policy Name: Sedative Hypnotics	
<p>Type of Submission – <u>Check all that apply:</u></p> <p> <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review - No Revisions <input checked="" type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i> </p>	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any changes or clarifying information for the policy below:</p> <p>Q1 2022: policy revised according to DHS revisions effective 01/03/2022.</p>	
<p>Name of Authorized Individual (Please type or print):</p> <p>Venkateswara R. Davuluri, MD</p>	<p>Signature of Authorized Individual:</p> 

Clinical Policy: Sedative Hypnotics

Reference Number: PHW.PDL.054

Effective Date: 01/01/2020

Last Review Date: 10/2021

[Revision Log](#)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Sedative Hypnotics are **medically necessary** when the following criteria are met:

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 member 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]) (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]) 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 member 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.

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 member:

1. For a Sedative Hypnotic benzodiazepine for a member 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,
 - vi. Catatonia
 - 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 member'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
 - 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 member 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 member'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 PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 member:

1. For a Sedative Hypnotic benzodiazepine for a member 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,
 - vi. Catatonia
 - 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 member'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 PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 member.

D. Approval Duration:

- **New Request: 6 months**
- **Renewal Request: 12 months**

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021