

Clinical Policy: Sedative Hypnotics

Reference Number: PHW.PDL.054

Effective Date: 01/01/2020

Last Review Date: 11/2025

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 PA Health & 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.
2. A Sedative Hypnotic with a prescribed quantity that exceeds the quantity limit.
3. A non-benzodiazepine Sedative Hypnotic when there is a record of a recent paid claim for another non-benzodiazepine Sedative (therapeutic duplication).
4. 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).
5. 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.
6. A Sedative Hypnotic benzodiazepine when prescribed for a member under 21 years of age.
7. 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.

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, **one** of the following:

- a. Has a history of therapeutic failure of a 6-month trial of melatonin
 - b. Has a contraindication or an 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 of or a contraindication or an intolerance to 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 history of therapeutic failure of the same regular-release Sedative Hypnotic; **AND**

5. For therapeutic duplication of a non-benzodiazepine Sedative Hypnotic, **one** of the following:

- a. Is being titrated to or tapered from another non-benzodiazepine Sedative Hypnotic

- b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

- 6. 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 medical literature or national treatment guidelines;

AND

- 7. When there is a record of 2 or more paid claims for any benzodiazepine within the past 30 days, **both** of the following:
 - a. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical 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

- 8. 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

- 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 the guidelines set forth in PA.CP.PMN.59 Quantity Limit Overrides.

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 a positive clinical response to the medication; **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 the guidelines set forth in PA.CP.PMN.59 Quantity Limit Overrides.

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 |
| Q1 2022: policy revised according to DHS revisions effective 03/07/2022. | 03/2022 |
| Q1 2023 annual review: no changes. | 11/2022 |
| Q1 2024: policy revised according to DHS revisions effective 01/08/2024 | 11/2023 |
| Q1 2025 annual review: no changes. | 11/2024 |
| Q1 2026 annual review: no changes. | 11/2025 |