Gateway Health It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

# 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.

## 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,
      iv. Spastic disorder,
      v. Dystonia

   b. Is receiving palliative care;

   **AND**

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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
   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)

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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;

   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,
      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;

   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.

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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.

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# NON-PREFERRED MEDICATION PRIOR AUTHORIZATION FORM *(form effective 01/01/20)*

| | | | |
|---|---|---|---|
| ☐New request ☐Renewal request | # of pages: _____ | Prescriber name: | |
| Name of office contact: | | Specialty: | |
| Contact's phone number: | | NPI: | State license #: |
| LTC facility contact/phone: | | Street address: | |
| Beneficiary name: | | Suite #: | City/State/Zip: |
| Beneficiary ID#: | DOB: | Phone: | Fax: |

Please refer to https://papdl.com/preferred-drug-list for the list of preferred and non-preferred medications in each Preferred Drug List class.

| | | | |
|---|---|---|---|
| Non-preferred medication name: | | Dosage form: | Strength: |
| Directions: | | Quantity: | Refills: |
| Diagnosis *(submit documentation)*: | | Dx code (*required*): | |

Has the beneficiary taken the requested non-preferred medication in the past 90 days? *(submit documentation)*…… ☐Yes ☐No

Describe all applicable medical reasons the beneficiary cannot use the preferred medication(s) in the same Preferred Drug List class. *Submit documentation (e.g., recent chart/clinic notes, diagnostic evaluations, lab results, etc.) supporting this non-preferred request.*

☐Treatment failure or inadequate response with preferred medication(s) *(include drug name, dose, and start/stop dates)*:

_____

_____

☐Unacceptable side effects, hypersensitivities, or other intolerances to preferred medication(s) *(include description and drug name(s))*:

_____

_____

☐Contraindication to preferred medication(s) *(include description and drug name(s))*:

_____

_____

☐Unique clinical or age-specific indications supported by FDA approval or medical literature *(describe)*:

_____

_____

☐Absence of preferred medication(s) with appropriate formulation *(list medical reason formulation is required)*:

_____

_____

☐Drug-drug interaction with preferred medication(s) *(describe)*:

_____

_____

☐Other medical reason(s) the beneficiary cannot use the preferred medication(s) *(describe)*:

_____

_____

☐For renewal requests of previously approved medications, submit documentation of tolerability and beneficiary's clinical response.

## PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

| | |
|---|---|
| Prescriber Signature: | Date: |