## 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.

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|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 11/01/2018** |
| **Policy Number: PA.CP.PST.16** | **Effective Date: 10/17/2018**<br>**Revision Date: 10/17/2018** |
| **Policy Name: Sedative Hypnotics** | **HC Approval Date:** |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

This policy is being retired and replaced by the following policy:

**PA.CP.PMN.16 Request for Medically Necessary Drug not on the PDL**

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| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:** |

# Clinical Policy: Sedative Hypnotics

Reference Number: PA.CP.PST.16
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

Coding Implications
Revision Log

**Description**
Sedative hypnotics include benzodiazepines, tricyclic antidepressants, melatonin receptor agonists, orexin receptor antagonist, a gamma-aminobutyric acid (GABA) agonist, and non-benzodiazepine agents. The following sedative hypnotics require prior authorization: zolpidem (Edluar®, Intermezzo®, Zolpimist), zolpidem CR (Ambien CR®), ramelteon (Rozerem®), doxepin (Silenor®), quazepam (Doral®), suvorexant (Belsomra®), eszopiclone (Lunesta®), and temazepam (Restoril® 7.5 and 22.5 mg capsules).

**FDA approved indication**
- Sedative hypnotics are indicated for insomnia.
  Limitation of use:
  - Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking

**Policy/Criteria**
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria**

It is the policy of Pennsylvania Health and Wellness ® that non-PDL sedative hypnotics are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Step Therapy for non-PDL Sedative Hypnotics** (must meet all)**:**

1. Age ≥ 18 years;
2. Failure of 2 PDL sedative hypnotics at therapeutic doses, each trialed for ≥ 14 days unless member experiences clinically significant adverse effects or has contraindication(s) to all PDL sedative hypnotics;
3. Requested dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 3 months**

**II. Continued Therapy**

**A. Step Therapy for Sedative Hypnotics** (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies;
2. Member is not receiving more than one sedative hypnotic;
3. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 6 months**

**III. Diagnoses/Indications for which coverage is NOT authorized:**
N/A

**IV. Appendices/General Information**
*Appendix A: Abbreviation Key*
FDA: Food and Drug Administration
GABA: gamma-aminobutyric acid
PDL: preferred drug list

**V. Dosage and Administration**

| Drug | Recommended Dose | Maximum Dose |
|---|---|---|
| Edluar (zolpidem) | 5 mg to 10 mg per day | 10 mg per day |
| Intermezzo (zolpidem) | 1.75 mg per night in women and 3.5 mg per night in men | 1.75 mg per night in women and 3.5 mg per night in men |
| Rozerem (ramelteon) | 8 mg per night | 8 mg per day |
| Silenor (doxepin) | 6 mg per day | 6 mg per day |
| Ambien CR (zolpidem CR) | 6.25 mg for women and 6.25 or 12.5 mg for men once per night | 12.5 mg per day |
| Zolpimist (zolpidem) | 5 mg for women and 5 or 10 mg for men once per night | 10 mg per day |
| Restoril (temazepam) | 7.5mg to 15 mg per day | 30 mg per day |
| Doral (quazepam) | 7.5 mg per day | 15 mg per day |
| Belsomra (suvorexant) | 10 mg per night | 20 mg per day |
| Lunesta (eszopiclone) | 1 mg per night | 3 mg per day |

**VI. Product Availability**

| Drug | Availability |
|---|---|
| Edluar (zolpidem) | 5 mg, 10 mg sublingual tablets |
| Intermezzo (zolpidem) | 1.75 mg, 3.5 mg sublingual tablets |
| Rozerem (ramelteon) | 8 mg tablet |
| Silenor (doxepin) | 3 mg, 6 mg tablets |
| Zolpidem CR | 6.25 mg, 12.5 mg tablets |
| Zolpimist (zolpidem) | 5mg/actuation oral spray |
| Restoril (temazepam) | 7.5 mg, 22.5 mg capsules |
| Doral (quazepam) | 15 mg tablets |
| Belsomra (suvorexant) | 5 mg, 10 mg, 15 mg, 20 mg tablets |
| Lunesta (eszopiclone) | 1 mg, 2 mg, 3 mg tablets |

**VII. Workflow Document**

1. Clinical Pharmacology. Tampa, FL: Gold Standard; 2008. Available at www.clinicalpharmacology.com. Accessed September 2, 2016.

| Reviews, Revisions, and Approvals | Date | Approval Date |
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