Division: Pharmacy Policy	Subject: Prior Authorization Criteria (Sedative/Hypnotics)
Original Development Date: Original Effective Date: Revision Date:	March 9, 2011 November 29, 2011; February 9, 2012, June 6, 2012; March 28, 2013; March 19, 2014, November 23, 2015, November 2, 2016, February 27, 2019, December 16, 2020, September 28, 2021, January 7, 2022, August 2, 2022, October 14, 2022, February 9, 2024, November 13, 2024

Sedative/Hypnotics

Preferred Agents: Estazolam, Eszopiclone, Lorazepam, Ramelteon, Temazepam 15mg and 30mg, Zaleplon, Zolpidem tartrate tablets

Non-preferred Agents: Ambien®, Belsomra®, Dayvigo™, Edluar®, Flurazepam, Loreev XR™, Lunesta®, Midazolam, Quviviq, Restoril™, Rozerem, Silenor® (Doxepin), Temazepam 7.5mg and 22.5mg (Restoril™), Triazolam (Halcion®), Zolpidem tartrate capsules, and Zolpidem tartrate ER (Ambien CR®), Heltioz® (tasimelteon - see separate) criteria)

LENGTH OF AUTHORIZATION: UP TO 90 DAYS

CLINICAL NOTES:

In the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) insomnia disorder is characterized by complaint of dissatisfaction with quantity or quality of sleep occurring at least 3 nights a week for at least 3 months, associated with one or more of the following:

- Difficulty falling asleep
- Difficulty staying asleep, with frequent awakenings or difficulty falling back asleep
- Early morning awakening

Cognitive Behavior Therapy (CBT) is a group of techniques that regardless of predisposing or precipitating factors is used to remove factors that exacerbate chronic insomnia, such as poor sleep habits, hyperarousal, irregular sleep schedules, inadequate sleep hygiene, and misconceptions about sleep and the consequences of insomnia. While CBT is most effective for insomnia disorder, it can also be effective for comorbid insomnia as adjunctive therapy.

REVIEW CRITERIA:

- **If request is for override of current quantity limit (30 every 30 days) deny request and provide notice of quantity limit.** [***Exception***: Ativan (lorazepam) quantity limit is 150 every 27 days with maximum of 5 allowed a day]
- Must be age 18 years or older.
- Must submit medical records verifying diagnosis of insomnia disorder (difficulty initiating sleep, maintaining sleep, or early morning disorder) for at least one month with significant impairment of daytime functioning
- Must have documented one month treatment failure (claims history or progress notes) of at least two of the above preferred agents **(zolpidem must be one of those trials)** within the past 90 days
- Must provide medical documentation verifying CBT within the past 365 days which must include education on sleep hygiene (habit) improvements. Other CBT measures may include stimulus control therapy, sleep restriction therapy, and relaxation therapy.

  Sleep Hygiene Improvements

  1) Going to bed and rising at the same time every day;

2) Avoiding stimulants (caffeine, nicotine, methylphenidate, dextroamphetamine, phenylephrine, and pseudoephedrine, etc.);
3) Avoiding daytime naps;
4) Avoiding alcohol;
5) Setting a comfortable environment (not too hot, cold, or noisy);
6) No exercise at night

- If request is for Ambien CR:
  - Above criteria must be met
  - Request must be for sleep maintenance
  - Medication must be prescribed as adjunctive therapy to cognitive behavior therapy

CONTINUATION OF THERAPY:

- **If request is for override of current quantity limit (30 every 30 days) deny request and provide notice of quantity limit.** [***Exception***: unless otherwise specified in the Summary of Limitations.]
- **Before continuation of Rozerem is approved:**
  - **The patient must be tapered with a three-month trial of cognitive behavior therapy only.** *(Note: Requests for continuation of Rozerem may be approved for up to 90 days. However, Rozerem requests to allow for tapering, may be approved for no more than one month)* **-OR-**
  - **The patient must have a two-month trial of preferred agents -OR-**
  - **Medical documentation from sleep specialist with recommendation to resume therapy must be submitted.**
- **The other non-preferred agents (excluding Rozerem) may be approved only two times within one year (365 days) collectively.** ***(For example, a patient may not have two authorizations for Belsomra and two authorizations for Lunesta with the same 365-day period.)***

DOSING AND ADMINISTRATION:

- Refer to product labeling https://www.accessdata.fda.gov/scripts/cder/daf/