



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

Sedative /Hypnotics

LENGTH OF AUTHORIZATION: UP TO 90 DAYS

CLINICAL NOTES:

In the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)* insomnia is characterized by one or more of these sleep complaints, which cause clinically significant impairment of daytime functioning:

- Difficulty initiating sleep
- Difficulty maintaining sleep
- Nonrestorative sleep

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 primary insomnia, it can also be effective for comorbid insomnia as adjunctive therapy.

REVIEW CRITERIA:

INITIATION OF THERAPY:

- **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 (difficulty initiating sleep, maintaining sleep, or nonrestorative sleep) 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 following preferred agents (**zolpidem must be one of those trials**) within the past 90 days:
 - Lorazepam (generic for Ativan)
 - Temazepam (except for 7.5 & 22.5mg)
 - Zolpidem (generic for Ambien, Edluar, Intermezzo, Zolpimist)



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- Must provide medical documentation verifying cognitive behavior therapy (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: Ativan (lorazepam) quantity limit is 150 every 27 days with maximum of 5 allowed a day*]
- **Before continuation of Rozerem and Lunesta is approved the patient must be tapered with a three month trial of cognitive behavior therapy only.** (*Requests for continuation of Rozerem and Lunesta to allow for tapering may be approved for no more than one month. -OR-*)
- **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 and Lunesta) may be approved only two times within one year (365 days) collectively.** (*For example, a patient may not have two authorizations for Doral and two authorizations for Estrazolam with the same 365 day period.*)



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DOSING:

- **Ambien (zolpidem)** – adults: 5mg or 10 mg by mouth at bedtime (men), 5mg (women); elderly: 5mg by mouth at bedtime
- **Ambien CR (zolpidem)** – adults: 6.25mg or 12.5mg by mouth at bedtime (men), 6.25 mg (women); elderly: 6.25mg by mouth at bedtime
- **Belsomra (suvorexant)** – adults: 10mg by mouth at bedtime (maximum of 20mg per day)
- **Dalmane (flurazepam)** - adults and adolescents 15 years of age and older: 30mg by mouth at bedtime; elderly: initially, 15 mg by mouth at bedtime
- **Doral (quazepam)** - adult: initially, 15mg or 7.5mg by mouth at bedtime; elderly: initially, 7.5mg by mouth at bedtime
- **Edluar (zolpidem)** - adults: 5mg or 10mg sublingual at bedtime (men), 5mg (women)
- **Intermezzo (zolpidem)** – adult: 1.75 mg SL (women), 3.5 mg (men) taken only once per night as needed if a middle-of-the-night awakening (only if the patient has at least 4 hours of bedtime remaining before the planned time of waking).
- **Lunesta (eszopiclone)** - adults: 2mg by mouth at bedtime - may increase to 3mg by mouth at bedtime; elderly: 1mg by mouth at bedtime initially; not to exceed 2mg by mouth at bedtime
- **Prosom (estazolam)** – adult: 1mg to 2mg by mouth at bedtime; elderly: 0.5mg to 1 mg by mouth at bedtime
- **Restoril (temazepam)** – adult: 15mg to 30 mg by mouth at bedtime; elderly 7.5-15 mg by mouth at bedtime
- **Rozerem (ramelteon)** – adult: 8 mg by mouth 30 min before bedtime on empty stomach
- **Sonata (zaleplon)** – adults: 10mg by mouth at bedtime; elderly: 5mg by mouth at bedtime (doses over 10mg are not recommended in elderly)
- **Zolpimist (zolpidem)** – adults: 1-2 (5-10 mg) sprays directly in mouth over tongue at bedtime (men), 1(5mg) spray (women)