Sedative and Hypnotic Drug Therapy Policy

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the sedative and hypnotic drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. Currently in the US, several non-benzodiazepine hypnotics for insomnia are available (e.g. zolpidem, zaleplon, ramelteon, tasimelteon, eszopiclone, and zolpidem CR). With the exception of Belsomra (suvorexant), Dayvigo (lemborexant), and Quviviq (daridorexant), orexin receptor antagonists; ramelteon and Hetlioz (tasimelteon), dual acting melatonin receptor agonists (MT_1 and MT_2 agonists); and Silenor (doxepin) a tricyclic with a proposed mechanism of action as a H_1 receptor antagonist, the rest of the agents work through gamma-aminobutyric (GABA) receptors. While all of the aforementioned agents are approved for treatment of insomnia, their specific FDA indications are noted below.

FDA-Approved Indications

- **Belsomra (suvorexant):** For the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
- **Dayvigo (lemborexant):** For the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
- **Edluar (zolpidem tartrate):** Sublingual formulation for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
- **Hetlioz (tasimelteon):** For the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 3 years of age and older.
- **Intermezzo (zolpidem tartrate):** For use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

- **Quviviq (daridorexant):** For the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
- **Rozerem (ramelteon):** For the treatment of insomnia characterized by difficulty with sleep onset.
- **Silenor (doxepin):** For the treatment of insomnia characterized by difficulties with sleep maintenance.
- **Zolpimist (zolpidem tartrate):** Oral solution spray for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

POLICY

Required Documentation:

Submission of the following information is necessary to initiate the prior authorization review on **Hetlioz**:

A. For Inital therapy, chart notes or test results to support one of the following:
   1. Total blindness in both eyes, OR
   2. Smith-Magenis Syndrome
B. For continuation of therapy, documentation to support one of the following:
   1. For Non-24-Hour Sleep-Wake Disorder, both of the following:
      i. Chart notes or test results confirming total blindness in both eyes
      ii. An increased total nighttime sleep and/or decreased daytime nap duration, OR
   2. For nighttime sleep disturbances in Smith-Magenis syndrome:
      i. Chart notes or test results confirming Smith-Magenis Syndrome
      ii. Improvement in quality of sleep such as improvement in sleep efficiency, sleep onset and final sleep offset, or waking after sleep onset.

Criteria for Initial Approval

I. **Hetlioz** may be considered **medically necessary** for the treatment of Non-24-Hour Sleep-Wake Disorder when all of the following criteria are met:
   - The patient has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas)
   - The patient is not able to perceive light in either eye
   - The member is experiencing difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness.

   Approval will be for **6 months**

II. **Hetlioz** may be considered **medically necessary** for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome when all of the following criteria are met:
   - Patient is ≥ 3 years of age
   - The patient has a confirmed clinical diagnosis of Smith-Magenis syndrome
   - The member has a history of sleep disturbances

   Approval will be for **6 months**

III. **Belsomra, Dayvigo, and Quviviq** may be considered **medically necessary** for the treatment on insomnia when all of the following criteria are met:
   - Patient is ≥ 18 years of age
   - Potential causes of sleep disturbances have been addressed such as sleep hygiene, sleep environment and medical or physiologic causes of chronic insomnia
   - Patient has tried and failed at least TWO of the generically available sedative hypnotics (zolpidem or zolpidem ER, eszopiclone, zaleplon) unless the patient is currently receiving a

positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)

Approval will be for **12 months**

IV. Brand and generic **Silenor (doxepin) and Rozerem (ramelteon)** may be considered **medically necessary** for the treatment of insomnia when all the following criteria are met:
- Patient is ≥ 18 years of age
- Potential causes of sleep disturbances have been addressed such as sleep hygiene, sleep environment and medical or physiologic causes of chronic insomnia
- The patient has tried and failed at least TWO of the generically available sedative hypnotics (zolpidem or zolpidem ER, eszopiclone, zaleplon) unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)

Approval will be for **12 months.**

V. **Edluar and Zolpimist** may be considered **medically necessary** for the treatment of short term insomnia with difficulty of sleep initiation when all the following criteria are met:
- Patient is ≥ 18 years of age
- Potential causes of sleep disturbances have been addressed such as sleep hygiene, sleep environment and medical or physiologic causes of chronic insomnia
- Patient is unable to swallow capsules/tablets related to a medical condition (including but not limited to: stroke, multiple sclerosis, muscular dystrophy, Parkinson's disease, scleroderma, diverticula, post-polio syndrome, polymyositis and dermatomyositis.

Approval will be for **12 months.**

VI. Brand and generic **Intermezzo (zolpidem tartrate)** may be considered **medically necessary** for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty in returning to sleep when all of the following criteria are met:
- Patient is ≥ 18 years of age
- Potential causes of sleep disturbances have been addressed such as sleep hygiene, sleep environment and medical or physiologic causes of chronic insomnia
- The initial starting dose of 1.75mg is not exceeded in patients that are female, over age 65 years or taking concomitant CNS depressants such as opioids, benzodiazepines, tricyclics or alcohol

Approval will be for **12 months.**

VII. **Belsomra, Dayvigo, Edluar, Hetlioz, Intermezzo, Rozerem, Silenor, Quviviq, Zolpimist, and any generic equivalents** are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Continuation of Therapy

I. The continuation of Belsomra, Dayvigo, Edluar, Intermezzo, Rozerem, Silenor, Quviviq, Zolpimist, and any generic equivalents may be considered **medically necessary** when the Criteria for Initial Approval above is met and the patient has a documented positive clinical response to therapy.

II. The continuation of **Hetlioz** may be considered **medically necessary** when the Criteria for Initial Approval above is met AND when all of the following criteria are met:
- The patient has a diagnosis of total blindess in both eyes (e.g., nonfunctioning retinas)
- The patient is not able to perceive light in either eye
- The patient is experiencing increased total nightime sleep and/or decreased daytime nap duration

Approval will be for **12 months**

III. **Hetlioz** may be considered **medically necessary** for the continued treatment of nighttime sleep disturbances in Smith-Magenis syndrome if the patient experiences improvement in the quality of sleep since starting therapy with Hetlioz.

Approval will be for **12 months**

Quantity Limits
- Belsomra 30 tablets/30 days
- Dayvigo 30 tablets/30 days
- Hetlioz 30 capsules/30 days
- Hetlioz oral suspension: 5 mL/day
- Quviviq 30 tablets/30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.
- Code(s), if applicable.

REFERENCES

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POLICY HISTORY

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