Rozerem

Description

Rozerem (ramelteon)

Background
Rozerem is a hypnotic (sleep) medicine that works by acting on melatonin receptors, which are thought to be important in maintaining a normal sleep-wake cycle. Melatonin is a natural substance produced by your body to help regulate your sleep-wake cycle. Since Rozerem has no affinity for GABA receptors, it does not work like other sedative hypnotics such as benzodiazepines. It is intended for use in adults for the treatment of the symptom of trouble falling asleep from insomnia (1).

Regulatory Status
FDA-approved indication: Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset (1).

Although Rozerem is not a controlled substance, CNS and cognitive effects have been reported with normal use. Symptoms such as hallucinations, bizarre behavior, agitation and mania have been reported. As with other hypnotic medications, complex behaviors may also occur during sleep and while the patient is minimally aware, including driving, eating food, and making phone calls (1).

Rozerem should be used with caution in patients with moderate hepatic impairment and is not recommended for use in patients with severe hepatic impairment (1).
Rozerem should not be used in children as it has been associated with potential changes in reproductive hormones in adults (1).

The safety and effectiveness of Rozerem in pediatric patients below the age of 18 years have not been established (1).

Related policies
Belsomra, Hetlioz, Sedative Hypnotics

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rozerem may be considered medically necessary in patients that are 18 years of age and older for the treatment of sleep onset insomnia and if the conditions indicated below are met.

Rozerem is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older

Diagnosis
Patient must have the following:

Sleep onset insomnia

AND NONE of the following:
1. Severe hepatic impairment (Child-Pugh Class C)
2. Concurrent therapy with another sedative hypnotic agent or Xyrem (sodium oxybate)

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines
Pre - PA Allowance

Age 18 years of age and older

Quantity 30 tablets per 365 days
Duration 12 months

Prior - Approval Limits

Quantity 90 tablets per 90 days
Duration 12 months

Prior – Approval Renewal Limits

Quantity 90 tablets per 90 days
Duration 12 months

Rationale

Summary
Rozerem is a melatonin receptor agonist used to treat the symptom of trouble falling asleep from insomnia. Rozerem should be used with caution in patients with moderate hepatic impairment and is not recommended for use in patients with severe hepatic impairment. The safety and effectiveness of Rozerem in pediatric patients below the age of 18 years have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Rozerem while maintaining optimal therapeutic outcomes.

References

Policy History

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### 5.60.07

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- **March 2015**: Annual editorial review and reference update
- **September 2016**: Annual editorial review  
  - Addition of no concurrent use with Xyrem  
  - Policy number change from 5.07.12 to 5.60.07
- **December 2017**: Annual review
- **November 2018**: Annual review
- **February 2019**: Addition of age limit for Pre-PA
- **March 2019**: Annual review and reference update

**Keywords**

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.