BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.60.007

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	June 27, 2014
Subject:	Rozerem	**Page:**	1 of 5

Last Review Date: September 6, 2024

Rozerem

Description

Rozerem (ramelteon)

Background
Rozerem (ramelteon) 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 patients less than 18 years of age have not been established (1).

Related policies
Hetlioz, Orexin Antagonists, Sedative Hypnotics, Xyrem, Xywav

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** if the conditions indicated below are met.

Rozerem may be considered **investigational** 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 Prior Authorization (PA) sleep aid (see Appendix 1) or with an oxybate product (see Appendix 2)

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

Same as above

Rationale

Summary

Rozerem (ramelteon) 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 patients less than 18 years of age 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

1. Rozerem [package insert]. Deerfield, IL: Takeda, Inc.; November 2021.

Policy History

Date	Action
June 2014	New addition to PA

September 2014	Annual review
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
May 2020	Revised no dual therapy requirement
June 2020	Annual review
March 2021	Annual editorial review
May 2021	Revised no dual therapy requirement
June 2021	Annual review. Revised Appendix 1
September 2022	Annual editorial review. Added Quviviq to Appendix 1
September 2023	Annual review
December 2023	Annual review and reference update
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

Appendix 1 - List of Prior Authorization (PA) Sleep Aids

Generic Name	Brand Name
daridorexant	Quviviq
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
quazepam	Doral
ramelteon	Rozerem
tasimelteon	Hetlioz
suvorexant	Belsomra
temazepam	Restoril
triazolam	Halcion
zaleplon	Sonata
zolpidem	Ambien
zolpidem extended-release	Ambien CR
zolpidem oral spray	Zolpimist
zolpidem sublingual	Edluar
zolpidem sublingual	Intermezzo

Appendix 2 - List of Oxybate Products

Generic Name	Brand Name
sodium oxybate	Xyrem
calcium, magnesium, potassium, sodium oxybates	Xywav