

Clinical Pharmacy Program Guidelines for Rozerem

Program	Prior Authorization
Medication	Rozerem (ramelteon)
Markets in Scope	California, Hawaii, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

2. Coverage Criteria:

A. Authorization

1. **Rozerem** will be approved based on **one** of the following criteria:

a. History of trial and failure of at least 2 weeks, contraindication, or intolerance to **both** of the following sedative-hypnotic alternatives:

(1) Zolpidem (generic Ambien)
(2) Zaleplon (generic Sonata)

-OR-

b. History of or potential for a substance abuse disorder

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

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- Supply limits may be in place.

4. References:

1. Rozerem Prescribing Information. Takeda Global; Deerfield, IL. December 2018.

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Change Control	
Date	Change
9/2009	Criteria taken from previously approved Unison policy, Sedatives / Hypnotics. Removed automated step process and zaleplon listing. Policy reformatted and renamed to Rozerem.
12/2010	Annual Review, no changes
9/2011	Annual Review, no changes
9/2012	Annual Review, no changes
12/2015	Annual Review, no changes
11/2016	Updated clinical criteria to align with Employer and Individual's policy except products for trial/failure differ and updated policy template
3/2017	Annual review. Updated policy template.
3/2018	Annual review.
3/2019	Annual review, updated references.
4/2020	Annual review, added Additional Clinical Rules section.