

Clinical Pharmacy Program Guidelines for Rozerem

Program	Prior Authorization
Medication	Rozerem (ramelteon)
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

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

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p>1. Rozerem will be approved based on <u>one</u> of the following criteria:</p> <p style="margin-left: 40px;">a. History of trial and failure of at least 2 weeks, contraindication, or intolerance to <u>both</u> of the following sedative-hypnotic alternatives:</p> <p style="margin-left: 80px;">(1) Zolpidem (generic Ambien) (2) Zaleplon (generic Sonata)</p> <p style="text-align: center;">-OR-</p> <p style="margin-left: 40px;">b. History of or potential for a substance abuse disorder</p> <p>Authorization will be issued for 12 months.</p>

3. References:

1. Rozerem Prescribing Information. Takeda Global; Deerfield, IL. November 2010.

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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.