



Prior Authorization Approval Criteria

Rozerem (ramelteon)

Generic name: Ramelteon

Brand name: Rozerem

Medication class: Hypnotic

FDA-approved use: Treatment of insomnia characterized by difficulty with sleep onset.

Available dosage form: 8 mg tablet

Usual dose: 8mg to be taken 30 minutes prior to bedtime.

Duration of therapy: Indefinite

Criteria for use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed insomnia characterized by difficulty with sleep onset.
- Treatment failure on one of these products (oxazepam, temazepam, lorazepam, trazodone).
- Treatment failure on generic Ambien.
- Underlying physical or psychological conditions (including addiction, depression, anxiety, sleep apnea, restless leg syndrome, circadian issues, pain, GERD, etc.) have been ruled out or are being adequately treated.

Contraindications:

- Patients with a known hypersensitivity to ramelteon or any of the product ingredients.

Not approved if:

- Patient has any contraindications to the use of ramelteon.
- Patient does not meet the above-stated criteria.

Special considerations:

- A melatonin receptor agonist.
- Not a controlled substance.
- Helps people fall asleep, not stay asleep.
- Only Rozerem and Lunesta are not limited to short-term use.
- All hypnotics generally work within 30 mins.
- Only Ambien and Lunesta help people sleep longer.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/14/05

Revised: 12/08