



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **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).

### **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



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## **ROZEREM (ramelteon)**

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.