Hetlioz

Description

Hetlioz (tasimelteon)

Background
Hetlioz is a melatonin receptor agonist used to treat non-24-hour sleep-wake disorder common in totally blind people. Non-24 is a chronic circadian rhythm (body clock) disorder in the blind that causes problems with the timing of sleep. Those with the disorder may have difficulty falling asleep or staying asleep, and may wake up groggy or feeling as if they need more rest (1).

Regulatory Status
FDA-approved indication: Hetlioz is a melatonin receptor agonist indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) (1).

Dose adjustment is not necessary in patients with mild or moderate hepatic impairment. Hetlioz has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, Hetlioz is not recommended for use in patients with severe hepatic impairment (1).

The safety and effectiveness of Hetlioz in pediatric patients below the age of 18 years have not been established (1).

Related policies
Rozerem, Sedative Hypnotics
Hetlioz may be considered *medically necessary* in patients that are 18 years of age and older with Non-24-Hour Sleep-Wake Disorder and if the conditions indicated below are met.

Hetlioz is considered *investigational* in patients that are less than 18 years of age and for all other indications.

### Prior-Approval Requirements

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

- Non-24-Hour Sleep-Wake Disorder (Non-24)

**AND ALL** of the following:

1. Total blindness
2. Absence of severe hepatic impairment (Child-Pugh Class C)
3. **NO** concurrent therapy with another sedative hypnotic agent or Xyrem (sodium oxybate)

### Prior – Approval *Renewal* Requirements

Same as above

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Quantity**

90 capsules per 90 days

**Duration**

12 months
Hetlioz is a melatonin receptor agonist used to treat non-24-hour sleep-wake disorder most common in the totally blind. Non-24 is a chronic circadian rhythm (body clock) disorder in the blind that causes problems with the timing of sleep. Dose adjustment is not necessary in patients with mild or moderate hepatic impairment. Hetlioz has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, Hetlioz is not recommended for use in patients with severe hepatic impairment. The safety and effectiveness of Hetlioz in pediatric patients below the age of 18 years have not been established. Hetlioz is not approved for the treatment of chronic insomnia (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Hetlioz while maintaining optimal therapeutic outcomes.

References

Policy History
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<td>May 2014</td>
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<td>September 2014</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.