

tasimelteon (HETLIOZ)

Diagnosis Considered for Coverage:

- Non-24-Hour Sleep-Wake Disorder (Non-24 or N24SWD)
- Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

Coverage Criteria:

1. For diagnosis Non-24-Hour Sleep-Wake Disorder

Initial Request:

- Patient is at least 18 years of age, **and**
- Prescribed by or in consultation with a sleep specialist, **and**
- Patient cannot maintain a stable 24-hour sleep-wake pattern synchronized to 24 hour light-dark cycle, **and**
- Sleep-wake symptoms have been present for at least 12 weeks, **and**
- Patient's symptoms of insomnia cause functional impairment (i.e. daytime drowsiness, reduced daytime activity), **and**
- **For HetlioZ oral suspension:**
 - Patient is \leq 28 kg (62 lb) **or**
 - Patient is greater than 28 kg (62 lb) and unable to swallow a pill, **and**
- Dose does not exceed 20 mg per day.

Coverage Duration: 2 months

Reauthorization after 2 months:

- Patient has evidence of improved duration of total nighttime sleep from baseline, **and**
- Dose does not exceed 20 mg per day.

Coverage Duration: 6 months

Reauthorization after 6 months:

- Patient has evidence of improved duration of total nighttime sleep, **and**
- Dose does not exceed 20 mg per day.

Coverage Duration: 6 months

2. For Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

- Clinical confirmation of Smith-Magenis Syndrome (SMS), **and**

- **For Hetlioz oral suspension:**
 - Patient is \leq 28 kg (62 lb) or
 - Patient is greater than 28 kg (62 lb) and unable to swallow a pill,
and
- Dose does not exceed 20 mg per night.

Coverage Duration: one year

Effective Date: 11/29/2023