blue of california

HETLIOZ (tasimelteon, oral)

Diagnosis Considered for Coverage:
- Non-24-Hour Sleep-Wake Disorder
- Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

Coverage Criteria:

For diagnosis Non-24-Hour Sleep-Wake Disorder
- Patient is at least 18 years of age, **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 cannot perform normal daily activities due to irregular sleep pattern, **and**
- Inadequate response with Rozerem, **and**
- Dose does not exceed FDA label maximum.

For Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
- Provider attestation of clinical confirmation of Smith-Magenis Syndrome (SMS), **and**
- Dose does not exceed FDA label maximum, **and**
- For Hetlioz oral suspension:
  a. Patient is ≤ 28 kg (63 lb) or
  b. Patient is greater than 28 kg (63 lb) and unable to swallow a pill

Coverage Duration: Length of benefit

Effective: 09/01/2021