Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: August 26, 2014 Original Effective Date: Revision Date:	August 26, 2014 August 5, 2021, January 13, 2022

HETLIOZ® (tasimelteon) capsules and HETLIOZ LQ™ (tasimelteon) oral suspension

LENGTH OF AUTHORIZATION: UP TO 6 MONTHS

INITIAL REVIEW CRITERIA (ALL OF THE FOLLOWING MUST BE TRUE):

- If seeking approval for **Hetlioz® capsules**
  - Patient must be ≥18 years old.
  - Patient must have a diagnosis of Non-24-hour sleep-wake disorder ("non-24") documented in clinical notes or health conditions.

OR

  - Patient must be ≥16 years old
  - Patient has a diagnosis of Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
  - Patient must have confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is identified
- If seeking approval for **Hetlioz LQ™ oral suspension**
  - Patient must be 3 to 15 years old.
  - Patient must have a diagnosis of Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).
  - Patient must have confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is identified.
- Do NOT approve for insomnia

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING & ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Dosage Forms:
  - 20 mg capsule (**Hetlioz®**)
  - 4 mg/mL oral suspension (**Hetlioz LQ™**)