



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: August 26, 2014 Original Effective Date: Revision Date:	August 26, 2014

HETLIOZ® (tasimelteon)

LENGTH OF AUTHORIZATION: UP TO 6 MONTHS

CLINICAL NOTES:

Tasimelteon is a melatonin receptor agonist and is indicated to treat non-24-hour sleep-wake disorder (“non-24”) in totally blind individuals. Non-24-hour sleep-wake disorder (“non-24”) is a chronic circadian rhythm disorder that causes problems with the timing of sleep and sleep patterns of people who are totally blind. The National Organization for Rare Disorders (NORD) states that the condition is characterized by the failure of a person's biological clock to synchronize to a 24-hour day light-dark cycle because light does not enter their eyes. Those with the disorder may have difficulty falling or staying asleep, and may wake up feeling as if they need more rest. People with non-24 may find their sleep patterns reversed (e.g., needing to sleep during the day and to be awake at night). Due to differences in circadian rhythms, it can take weeks or months of daily use of tasimelteon before the patient experiences any benefit.

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

- Patient is ≥ 18 years old (safe and effective use in pediatric patients has not been established)
- Patient is totally blind
- Patient has a diagnosis of Non-24-hour sleep-wake disorder (“non-24”) documented in clinical notes or health conditions (ICD-9: 327.34)
- Do NOT approve for insomnia

DOSING & ADMINISTRATION:

- Dosage: 20 mg (1 capsule) taken once daily before bedtime, at the same time every night. Hetlioz should not be taken with food.
- Dosage Form: 20 mg capsule