ALASKA MEDICAID
Prior Authorization Criteria

Hetlioz®
(tasimelteon)

FDA INDICATIONS AND USAGE[1]

Hetlioz® is a melatonin receptor agonist indicated in the treatment of Non-24 Hour Sleep-Wake Disorder (Non-24). Non-24 is a chronic problem associated with the circadian rhythm in people that are deprived of light. Total blindness affects the ability to fall asleep, stay asleep, and wake up feeling as though they need more sleep. The body cannot recognize the 24 hour light-dark cycle, which is needed to synchronize one's internal clock.

APPROVAL CRITERIA[1,2,3,4]

1. Patient is 18 years of age or older **AND;**
2. Patient has a confirmed diagnosis of Non-24-hour Sleep-Wake disorder **AND;**
3. Patient is completely blind (i.e. no light perception) **AND;**
4. Prescribed by or in consultation with a sleep specialist **AND;**
5. Patient has tried and failed the use of melatonin under the guidance of a sleep specialist for at least 3 months or has an intolerance or contraindication to melatonin use **AND;**
6. Prescriber must submit chart notes showing a trial and failure of a prescribed sleep-wake schedule.

DENIAL CRITERIA[1,2,3,4]

1. Patient is less than 18 years of age **OR**;
2. Patient does not have confirmed diagnosis of Non-24-hour Sleep-Wake disorder **OR**;
3. Patient is not completely blind (i.e. no light perception) **OR**;
4. Not being prescribed by or in consultation with a sleep specialist **OR**;
5. Patient has not tried and failed the use of melatonin under the guidance of a sleep specialist for at least 3 months or does not have an intolerance or contraindication to melatonin use **OR**;
6. Prescriber has not submitted chart notes showing a trial and failure of a prescribed sleep-wake schedule.

CAUTIONS[1]

- Concomitant use should be avoided with strong CYP1A2 inhibitors and/or strong CYP3A4 inducers.
- Hetlioz® should be taken without food.
- Safety and effectiveness in pediatric patients has not been established.
- Smoking can reduce the effectiveness of Hetlioz®.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Re-authorization: up to 6 months with clinically meaningful chart notes showing the patient is responding positively to therapy.

QUANTITY LIMITS

- 30 – 20mg capsules per 30 days (1 capsule per day)

REFERENCES / FOOTNOTES:

1. Hetloiz® [Package Insert]. Vanda Pharmaceuticals Inc., Washington, D.C.; December 2014. Accessed at: http://www.hetlioz.com/pdf/HetliozPI.pdf. Accessed on: December 17, 2018.
2. Uchiyama M, Lockley SW. Non-24-hour sleep-wake syndrome in sighted and blind patients. *Sleep Med Clin*. 2009; 4:195-221.
3. Johnsa JD, Neville MW. Tasimelteon: a melatonin receptor agonist for non-24-hour sleep-wake disorder. Annals Pharmacotherapy. 2014;48(12):1636-1641.
4. Sack RL, Auckley D, Auger R, et al. Circadian rhythm sleep disorders: part II, advanced sleep phase disorder, delayed sleep phase disorder, free-running disorder, and irregular sleep-wake rhythm. An American Academy of Sleep Medicine review. Sleep. 2007;30(11):1484-1501.