ALASKA MEDICAID
Prior Authorization Criteria

Hetlioz®
(tasimelteon)

FDA INDICATIONS AND USAGE[1,2,6,7]

Hetlioz® is a melatonin receptor agonist indicated in the treatment of Non-24 Hour Sleep-Wake Disorder (Non-24) in patients 16 years of age and older and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 years of age and older. Non-24 is a chronic problem associated with the circadian rhythm in people, that affects the ability to fall asleep, stay asleep, and wake up feeling as though they need more sleep. There is a misalignment of the endogenous internal body clock, which disrupts the sleep wake cycle. Non–24-hour sleep-wake syndrome is characterized by a free-running sleep-wake rhythm. The sleep-wake cycle commonly remains constant in length but is > 24 hours, resulting in a delay of sleep and wake times by 1 to 2 hours each day.[2] SMS is a genetic disorder resulting from chromosome 17p11.2 microdeletions and is characterized by numerous congenital anomalies and intellectual disabilities.

APPROVAL CRITERIA[1,3,4,5,6,7]

Non-24-hour Sleep-Wake disorder [G47.24] [1,3,4,5,6]

1. Patient is 16 years of age or older and the request is for capsules **AND;**
2. Patient has the diagnosis of Non-24-hour Sleep-Wake disorder confirmed by actigraphy performed for 14 consecutive days, plus an evaluation of sleep logs recorded for ≥ 30 days, both submitted with the request **AND;**
3. Prescribed by or in consultation with a board certified sleep specialist **AND;**
4. Prescriber attests and provides documentation that the patient has been screened and treated, if indicated, for alternate sleep disorder conditions **AND;**
5. Prescriber must submit chart notes showing a trial and failure of a prescribed sleep-wake schedule **AND;**
6. For patients with sighted Non-24, the patient must have trialed light therapy for a period of 3 months.

Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) [Q93.88] [1,7]

1. Patient is 3 years of age to 15 years of age and the request is for Hetlioz® LQ **OR;**
2. Patient is 16 years of age or older and the request is for capsules **AND;**
3. Patient has the confirmed diagnosis of Smith-Magenis syndrome **AND;**
4. Prescribed by or in consultation with a board certified sleep specialist **AND;**
5. Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking, early waking, etc.) **AND;**
6. Prescriber must submit chart notes showing a trial and failure of a prescribed sleep-wake schedule and a minimum 30 days of sleep logs.

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DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR;**
2. The patient will be using with strong CYP1A2 inhibitors and/or strong CYP3A4 inducers concomitantly **OR;**
3. Patient has severe hepatic impairment (Child-Pugh Class C).

CAUTIONS[1]

- Hetlioz® should be taken without food.
- 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 combination Hetlioz® and light therapy based on minimum 14 day actigraphy after a minimum of 60 days of therapy and the last 30 days of sleep logs prior to reauthorization.

QUANTITY LIMITS

- 30 – 20mg capsules per 30 days (1 capsule per day)
- 1- 158ml bottle per 30 days
- 2- 48ml bottles per 30 days

REFERENCES / FOOTNOTES:

1. Hetlioz® [Package Insert]. Vanda Pharmaceuticals Inc., Washington, D.C.; December 2020. Accessed at: http://www.hetlioz.com/assets/HetliozPI.pdf. Accessed on: January 17, 2022.
2. Merck Manuals. Circadian Rhythm Sleep Disorders. [Internet] Kenilworth, NJ: Merck Manuals; June 2020 Accessed on: March 9, 2022. Accessed at: https://www.merckmanuals.com/professional/neurologic-disorders/sleep-and-wakefulness-disorders/circadian-rhythm-sleep-disorders
3. Malkani RG, Abbott SM, Reid KJ, Zee PC. Diagnostic and treatment challenges of sighted non-24-hour sleep-wake disorder. J Clin Sleep Med. 2018;14(4):603–613.
4. Uchiyama M, Lockley SW. Non-24-Hour Sleep-Wake Rhythm Disorder in Sighted and Blind Patients. Sleep Med Clin. 2015;10:495-516

5. Johnsa JD, Neville MW. Tasimelteon: a melatonin receptor agonist for non-24-hour sleep-wake disorder. Annals Pharmacotherapy. 2014;48(12):1636-1641.
6. 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.
7. The PRISMS Professional Advisory Board medical management guidelines for an individual diagnosed with SMS. © 2018 Parents and Researchers Interested in Smith-Magenis Syndrome, Inc. Available at: https://www.prisms.org/about-sms/living-with-sms/medical-management-guidelines./Accessed on January 18, 2022.