

Specialty Guideline Management tasimelteon-Hetlioz-Hetlioz LQ

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Hetlioz	tasimelteon
Hetlioz LQ	tasimelteon

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Non-24-Hour Sleep-Wake Disorder (Non-24)

Hetlioz capsules are indicated for the treatment of Non-24 in adults.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

- Hetlioz capsules are indicated for treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
- Hetlioz LQ oral suspension is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Reference number(s)
2426-A

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

Non-24-Hour Sleep-Wake Disorder (Non-24)

- Chart notes or medical record documentation confirming Non-24 (e.g., sleep logs, actigraphy).
- Chart notes or test results confirming total blindness in both eyes.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

- Chart notes, medical records, or laboratory results confirming Smith-Magenis Syndrome (SMS).

Continuation requests

Non-24-Hour Sleep-Wake Disorder (Non-24)

- Chart notes or test results confirming total blindness in both eyes.
- An increased total nighttime sleep and/or decreased daytime nap duration.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

- Chart notes, medical records, or laboratory results confirming Smith-Magenis Syndrome (SMS).
- Improvement in quality of sleep such as improvement in sleep efficiency, sleep onset and final sleep offset, or waking after sleep onset.

Prescriber Specialties

This medication must be prescribed by, or in consultation with, a sleep specialist (e.g., neurologist experienced with sleep disorders, physician certified in sleep medicine) or psychiatrist.

Coverage Criteria

Non-24-Hour Sleep-Wake Disorder (Non-24)¹⁻⁴

Authorization of 12 months may be granted for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adult members when all of the following criteria are met:

- The member has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24) (e.g., sleep log or actigraph evaluation).
- The member has total blindness in both eyes (e.g., nonfunctioning retinas).
- The member is not able to perceive light in either eye.
- The member is experiencing difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)^{1,5-7}

Authorization of 12 months may be granted for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in members 3 years of age or older when all of the following criteria are met:

Reference number(s)
2426-A

- The diagnosis of SMS is confirmed by genetic testing (e.g., heterozygous deletion of 17p11.2, heterozygous pathogenic variant involving RAI1).
- The member has a history of sleep disturbances.

Continuation of Therapy

Non-24-Hour Sleep-Wake Disorder (Non-24)¹⁻³

Authorization of 12 months may be granted for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) when all of the following criteria are met:

- The member has total blindness in both eyes (e.g., nonfunctioning retinas).
- The member is not able to perceive light in either eye.
- The member experiences increased total nighttime sleep and/or decreased daytime nap duration.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)¹

Authorization of 12 months may be granted for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) if the member experiences improvement in the quality of sleep since starting therapy with the requested drug.

References

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; January 2024.
2. Tasimelteon [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; January 2023.
3. Auger RR, Burgess HJ, Emens JS, et al. Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders: Advanced Sleep-Wake Phase Disorder (ASWPD), Delayed Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD). An Update for 2015: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2015;11(10):1199-1236.
4. National Organization for Rare Disorders (NORD). Non-24-Hour Sleep-Wake Disorder. Available at <https://rarediseases.org/rare-diseases/non-24-hour-sleep-wake-disorder/>. Accessed on December 5, 2025.
5. National Organization for Rare Disorders (NORD). Smith-Magenis Syndrome. Available at <https://rarediseases.org/rare-diseases/smith-magenis-syndrome/>. Accessed on December 12, 2025.
6. Polymeropoulos CM, Brooks J, Czeisler EL, et al. Tasimelteon safely and effectively improves sleep in Smith-Magenis syndrome: a double-blind randomized trial followed by an open-label extension. *Genetic Med*. 2021;23(12):2426-2432.
7. Smith ACM, Berens J, Boyd KE, et al. Smith-Magenis Syndrome. 2001 Oct 22 [Updated 2025 May 29]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. *GeneReviews* [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1310/>.