

Effective Date: 7/2018
Reviewed: 7/2018, 10/2019, 5/2020, 3/2021, 2/2022, 3/2023, 2/2024, 2/2025, 3/2026
Scope: Medicaid

## **HETLIOZ (tasimelteon) Oral Suspension TASIMELTEON Capsule**

### **POLICY**

#### **I. 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 Indication

- A. Tasimelteon capsules is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults.
- B. Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS):
  - a. Tasimelteon capsules are indicated for treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older
  - b. Hetlizo 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 are not a covered benefit.

#### **II. CRITERIA FOR INITIAL APPROVAL**

##### **A. Non-24-Hour Sleep-Wake Disorder**

Authorization of 6 months may be granted for treatment of Non-24-Hour Sleep-Wake Disorder when all of the following criteria are met:

- a. The requested drug must be prescribed by, or in consultation, with a sleep specialist or psychiatrist.
- b. Documentation that the member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
- c. Documentation that the member is NOT able to perceive light in either eye.
- d. Documentation that the member is experiencing difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness.
- e. The request is for the tasimelteon capsules.

##### **B. Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)**

Authorization of 6 months may be granted for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) when all of the following criteria are met:

- a. The requested drug must be prescribed by, or in consultation, with a sleep specialist or psychiatrist.
- b. Documentation that the member has a diagnosis of Smith-Magenis syndrome, with genetic test results provided, confirmed by the presence of one of the following genetic mutations: a heterozygous deletion of 17p11.2 OR a heterozygous pathogenic variant involving *RAI1*.

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- c. Documentation that the member has a history of sleep disturbances
- d. If requesting oral suspension, member must be between the ages of 3 and 15 years old.

#### IV. CONTINUATION OF THERAPY

##### A. Non-24-Hour Sleep-Wake Disorder

Authorization of 6 months may be granted for treatment of Non-24-Hour Sleep-Wake Disorder when all of the following criteria are met:

- a. Documentation that the member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
- b. Documentation that the member is NOT able to perceive light in either eye.
- c. Documentation that the member is experiencing increased total nighttime sleep and/or decreased daytime nap duration.
- d. The request is for the tasimelteon capsules.

##### B. Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

Authorization of 6 months may be granted for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome when all of the following criteria are met:

- a. Documentation that the member has a diagnosis of Smith-Magenis syndrome, with genetic test results provided, confirmed by the presence of one of the following genetic mutations: a heterozygous deletion of 17p11.2 OR a heterozygous pathogenic variant involving *RAI1*.
- b. Documentation that the member experiences improvement in the quality of sleep since starting therapy with Hetlioz.
- c. If requesting oral suspension, member must be between the ages of 3 and 15 years old.

#### III. QUANTITY LIMIT

Tasimelteon 20mg capsule: 1 capsule per day  
 Hetlioz 4mg/ml oral suspension: 5 ml per day

#### IV. REFERENCES

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2022. Accessed March 2026.
2. Auger, Robert R, Burgess, Helen J, 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 Oct;11(10):1199-236.