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

SPECIALTY GUIDELINE MANAGEMENT

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. 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 are not a covered benefit.

II. PRESCRIBER SPECIALTY

The requested drug must be prescribed by, or in consultation, with a sleep specialist or psychiatrist.

III. 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. 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 difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness.
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 (SMS) 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 has a history of sleep disturbances
c. 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.

IV. QUANTITY LIMIT

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

V. REFERENCES

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2022.
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.