Effective Date: 7/2018
Reviewed: 7/2018, 10/2019, 5/2020, 3/2021, 2/2022, 3/2023, 2/2024 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. DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

A. For initial therapy, chart notes and/or genetic test results to support one of the following:
    a. Total blindness in both eyes, OR
    b. Smith-Magenis Syndrome
B. For continuation of therapy, documentation to support one of the following:
    a. For Non-24-Hour Sleep-Wake Disorder, both of the following:
        i. Chart notes or test results confirming total blindness in both eyes
        ii. An increased total nighttime sleep and/or decreased daytime nap duration, OR
    b. For nighttime sleep disturbances in Smith-Magenis syndrome:
        i. Chart notes and genetic test results confirming Smith-Magenis Syndrome
        ii. Improvement in quality of sleep such as improvement in sleep efficiency, sleep onset and final sleep offset, or waking after sleep onset.

III. PRESCRIBER SPECIALTY

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

IV. 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 member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
b. The member is NOT able to perceive light in either eye.
c. 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. 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. 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. The member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
b. The member is NOT able to perceive light in either eye.
c. 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. 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. 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.

V. QUANTITY LIMIT

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

VI. 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.