AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Hetlioz	Page:	1 of 3
Effective Date:	7/15/2024	Last Review Date:	5/2024

Applies to:	☒Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☐Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Hetlioz (tasimelteon) under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

A. Non-24-Hour Sleep-Wake Disorder (Non-24):
   Hetlioz (tasimelteon) capsules are indicated for the treatment of Non-24 in adults

B. Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS):
   a. Hetlioz (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 not medically necessary.

Applicable Drug List:

Tasimelteon capsules
Hetlioz LQ suspension

Policy/Guideline:

Documentation:

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

A. For initial therapy, chart notes or 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 or 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.

Prescriber Specialty:

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.

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.

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 confirmed clinical diagnosis of Smith-Magenis syndrome
b. The member has a history of sleep disturbances

Criteria for Continuation of Therapy:

A. Non-24-Hour Sleep-Wake Disorder

Authorization of 12 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.

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

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

Approval Duration and Quantity Restrictions:

Approval:

- Initial Approval: 6 months
- Renewals: 12 months

Quantity Level Limit:

- Tasimelteon 20 mg capsules: 30 capsules per 30 days
- Hetlioz LQ oral suspension 4 mg/mL: 158 mL per day

References:

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; January 2023.
2. Tasimelteon [package insert]. Bridgewater, NJ.: Amneal Pharmaceuticals.; January 2023.
3. 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.