AETNA BETTER Coverage Policy		<b>⇔</b> aetna™		
Name:	Hetlioz		Page:	1 of 3
Effective Date:	6/9/2025		Last Review Date:	5/27/2025
Applies to:	⊠Illinois	⊠Florida Kids	⊠Pennsylvania Kids	;

### 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 Hetlioz capsules

## **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:**

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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:**

**Note:** Requests for brand Hetlioz capsules for members 16 years of age and older require that the member is unable to use generic tasimelteon capsules for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

## 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.

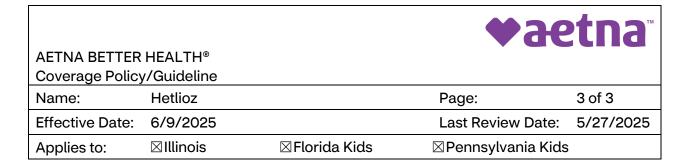
## B. Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

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:**

Hetlioz (tasimelteon) 20 mg capsules: 30 capsules per 30 days

Hetlioz LQ oral suspension 4 mg/mL: 5 mL per day

### **References:**

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