AETNA BETTER HEALTH [®] Coverage Policy/Guideline					
Name:	Hetlioz		Page:	1 of 3	
Effective Date: 7/15/2024			Last Review Date:	5/2024	
Applica	⊠Illinois	□Florida	⊠Florida Kids		
Applies to:	□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.

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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:

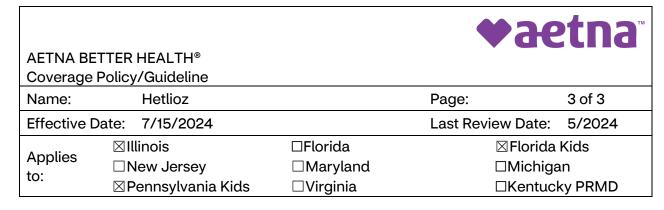
A. Non-24-Hour Sleep-Wake Disorder

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.
- 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.