



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: HetlioZ Page: 1 of 3

Effective Date: 12/21/2023 Last Review Date: 11/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> 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.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: HetlioZ

Page: 2 of 3

Effective Date: 12/21/2023

Last Review Date: 11/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

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:

- The member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
- The member is not able to perceive light in either eye.
- 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:

- The member has a confirmed clinical diagnosis of Smith-Magenis syndrome
- 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:

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



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Hetlioz

Page: 3 of 3

Effective Date: 12/21/2023

Last Review Date: 11/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

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: 5 mL per day

References:

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; January 2023.
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.