CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 2426-A |

# Specialty Guideline Management tasimelteon-Hetlioz-Hetlioz LQ

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Hetlioz | tasimelteon |
| Hetlioz LQ | tasimelteon |

## 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 Indications1,2

#### Non-24-Hour Sleep-Wake Disorder (Non-24):

Hetlioz capsules are indicated for the treatment of Non-24 in adults.

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

* Hetlioz capsules are indicated for treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
* 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.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### For initial requests, chart notes or test results to support one of the following:

* Total blindness in both eyes for Non-24 Hour Sleep-Wake Disorder (Non-24)
* Smith-Magenis Syndrome.

### For continuation requests, documentation to support one of the following:

* For Non-24-Hour Sleep-Wake Disorder, both of the following:
  + Chart notes or test results confirming total blindness in both eyes
  + An increased total nighttime sleep and/or decreased daytime nap duration
* For nighttime sleep disturbances in Smith-Magenis syndrome, both of the following:
  + Chart notes or test results confirming Smith-Magenis Syndrome
  + Improvement in quality of sleep such as improvement in sleep efficiency, sleep onset and final sleep offset, or waking after sleep onset.

## Prescriber Specialties

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.

## Coverage Criteria

### Non-24-Hour Sleep-Wake Disorder1-3

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.

### Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)1

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.

## Continuation of Therapy

### Non-24-Hour Sleep-Wake Disorder1-3

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 experiences increased total nighttime sleep and/or decreased daytime nap duration.

### Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)1

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

## References

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