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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	April 18, 2014
Subject:	Hetlioz	**Page:**	1 of 6

Last Review Date: December 13, 2024

Hetlioz

Description

Hetlioz (tasimelteon)

Background
Hetlioz (tasimelteon) is a melatonin receptor agonist used to treat certain sleep disorders. Hetlioz is an agonist at the melatonin MT_1 and MT_2 receptors which are thought to be involved in the control of circadian rhythms (1).

Regulatory Status
FDA-approved indications:
Hetlioz capsules are indicated for the treatment of: (1)

- Non-24-Hour Sleep-Wake Disorder (Non-24) in adults
- Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older

Hetlioz LQ oral suspension is indicated for the treatment of: (1)

- Nighttime sleep disturbances in SMS in pediatric patients 3 years to 15 years of age

Dose adjustment is not necessary in patients with mild or moderate hepatic impairment. Hetlioz has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, Hetlioz is not recommended for use in patients with severe hepatic impairment (1).

The safety and effectiveness of Hetlioz for the treatment of Non-24 in patients less than 18 years of age have not been established (1).

The safety and effectiveness of Hetlioz for the treatment of nighttime sleep disturbances in SMS have not been established in patients less than 3 years of age (1).

Related policies
Lumryz, Orexin Antagonists, Rozerem, Sedative Hypnotics, Xyrem, Xywav

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Hetlioz may be considered **medically necessary** if the conditions indicated below are met.

Hetlioz may be considered **investigational** for all other indications.

Prior-Approval Requirements

Hetlioz <u>capsules</u> only

Diagnoses

Patient must have **ONE** of the following:

1. Non-24-Hour Sleep-Wake Disorder (Non-24)
    a. 18 years of age or older
    b. Total blindness
2. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
    a. 16 years of age or older

AND ALL of the following:

a. **NO** severe hepatic impairment (Child-Pugh Class C)
b. **NO** concurrent therapy with another Prior Authorization (PA) sleep aid (see Appendix 1) or with an oxybate product (see Appendix 2)

Hetlioz <u>LQ oral suspension</u> only

Diagnosis

Patient must have the following:

1. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
    a. 3 to 15 years of age

AND ALL of the following:

a. **NO** severe hepatic impairment (Child-Pugh Class C)
b. **NO** concurrent therapy with another Prior Authorization (PA) sleep aid (see Appendix 1) or with an oxybate product (see Appendix 2)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Dosage form	Quantity
Hetlioz 20mg capsules	90 capsules per 90 days **OR**
Hetlioz LQ 4mg/mL oral suspension	474 mL per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Hetlioz (tasimelteon) is a melatonin receptor agonist used to treat certain sleep disorders. Hetlioz is an agonist at the melatonin MT_1 and MT_2 receptors which are thought to be involved in the control of circadian rhythms. The safety and effectiveness of Hetlioz for the treatment of Non-24 in patients less than 18 years of age have not been established. The safety and

effectiveness of Hetlioz for the treatment of nighttime sleep disturbances in SMS have not been established in patients less than 3 years of age (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Hetlioz while maintaining optimal therapeutic outcomes.

References

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; January 2024.

Policy History

Date	Action
May 2014	New addition to PA
May 2014	Addition to criteria that the patient must have total blindness
September 2014	Annual review
March 2015	Annual editorial review and reference update Addition of no concurrent therapy with another sedative hypnotic agent
September 2016	Annual editorial review and reference update Addition of no concurrent therapy with Xyrem (sodium oxybate) Policy code changed from 5.07.10 to 5.60.10
December 2017	Annual editorial review
November 2018	Annual review
December 2019	Annual review
May 2020	Revised no dual therapy requirement
June 2020	Annual review
January 2021	Addition of Hetlioz LQ oral suspension. Addition of new indication for both dosage forms: nighttime sleep disturbances in SMS
March 2021	Annual editorial review
May 2021	Revised no dual therapy requirement. Added Appendix 2
June 2021	Annual editorial review. Revised Appendix 1
June 2022	Annual editorial review
September 2022	Annual editorial review. Added Quviviq to Appendix 1
June 2023	Annual review and reference update
September 2023	Annual review
December 2023	Annual review

June 2024	Annual review and reference update
December 2024	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

Appendix 1 - List of Prior Authorization (PA) Sleep Aids

Generic Name	Brand Name
daridorexant	Quviviq
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
quazepam	Doral
ramelteon	Rozerem
tasimelteon	Hetlioz
suvorexant	Belsomra
temazepam	Restoril
triazolam	Halcion
zaleplon	Sonata
zolpidem	Ambien
zolpidem extended-release	Ambien CR
zolpidem oral spray	Zolpimist
zolpidem sublingual	Edluar
zolpidem sublingual	Intermezzo

Appendix 2 - List of Oxybate Products

Generic Name	Brand Name
sodium oxybate	Lumryz
sodium oxybate	Xyrem
calcium, magnesium, potassium, sodium oxybates	Xywav