Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Hetlioz (tasimelteon)

Effective: June 9, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Hetlioz (tasimelteon) is a melatonin receptor agonist.

Hetlioz capsules are indicated for the treatment of:

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

Clinical Guideline Coverage Criteria

1. Hetlioz (tasimelteon)

The plan may authorize coverage of Hetlioz (tasimelteon) for patients when **ALL** of the following criteria are met:

For management of Non-24 sleep-wake disorder:

1. Documentation the patient is totally blind (has no light perception)

AND

2. Documented diagnosis of Non-24 sleep-wake disorder

AND

3. Patient is 18 years of age or older

AND

4. Prescribed by a specialist in sleep disorders

AND

5. Trial and failure, inadequate response, intolerance, or contraindication to a trial of timed over-the-counter melatonin

For management of Smith-Magenis syndrome:

1. Documented diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome

AND

2. Patient is 16 years of age or older

AND

3. Prescribed by a specialist in sleep disorders

2. Hetlioz LQ oral suspension (tasimelteon)

The plan may authorize coverage of Hetlioz LQ oral suspension (tasimelteon) for patients when all of the following criteria are met:

1. Documented diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

AND

2. One of the following:
    a. Patient is 3 to 15 years of age

b. Patient is 16 years of age or older and the prescriber provides medical necessity for use

AND

3. Prescribed by a specialist in sleep disorders

Renewal Authorization for Hetlioz and Hetlioz LQ (tasimelteon):

1. Documented diagnosis of Non-24 sleep-wake disorder or SMS

AND

2. Documentation the patient is totally blind (has no light perception) if used for Non-24 sleep-wake disorder

AND

3. Prescribed by or in consultation with a specialist in sleep disorders

AND

4. Documentation of continued positive clinical response to therapy

Limitations

1. Initial authorization of Hetlioz (tasimelteon) and Hetlioz LQ oral suspension (Hetlioz) will be for a period of four (4) months. Reauthorization will be provided in 12-month intervals.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Hetlioz and Hetlioz LQ (tasimelteon) [prescribing information]. Washington, DC: Vanda Pharmaceuticals; January 2024.
2. Lockley SW, Dressman MA, Licamele L, et al. Tasimelteon for non-24-hour sleep-wake disorder in totally blind people (SET and RESET): two multicentre, randomised, double-masked, placebo-controlled phase 3 trials. Lancet 2015; 386:1754.
3. Auger RR, Burgess HJ, Emens JS, 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 15;11(10):1199-236. doi: 10.5664/jcsm.5100. PMID: 26414986; PMCID: PMC4582061.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: Administrative update with limitation added for a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions.
- June 11, 2024: No changes.
- June 10, 2025: No changes.
- June 9, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.