Pharmacy Medical Necessity Guidelines:
Hetlioz® (tasimelteon)

Effective: September 15, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Hetlioz (tasimelteon) is a melatonin receptor agonist. Hetlioz capsules are approved to treat non-24 hour sleep-wake disorder in totally blind individuals. Hetlioz capsules are also indicated for nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients who are 16 years of age and older.

Another formulation, **Hetlioz LQ oral suspension**, is indicated for the treatment of nighttime sleep disturbances in patients with SMS who are 3 to 15 years of age

COVERAGE GUIDELINES

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

Non-24 Sleep-Wake Disorder

1. Documentation the Member is totally blind

AND

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

AND

3. Hetlioz is prescribed by or in consultation with a sleep specialist

AND

4. The Member has had an inadequate response, intolerance, or contraindication to melatonin

AND

5. The request is for Hetlioz capsules

Smith-Magenis Syndrome:

1. The Member has a documented diagnosis of Smith-Magenis syndrome

AND

2. The prescriber is a sleep specialist or specialist in the treatment of Smith-Magenis syndrome

AND

3. **Members 3 to 15 years of age:** the request is for Hetlioz LQ oral suspension

AND

4. **Members 16 years of age and older:** the request is for Hetlioz capsules OR the prescriber indicates why the oral suspension is medically necessary for the member

Reauthorization:

Documentation the Member continues to have a positive clinical response to therapy

LIMITATIONS

1. The plan will not cover Hetlioz for the diagnosis of insomnia.
2. Initial authorization of Hetlioz (tasimelteon) will be for a period of four (4) months. Subsequent approvals will be for one year.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

4. The following quantity limitation applies:

Medication Name	Quantity Limit
Hetlioz (tasimelteon) capsules	30 capsules per 30 days
Hetlioz LQ (tasimelteon) oral suspension	158 mL bottle: 1 bottle per 30 days 48 mL bottle: 3 bottles per 30 days

CODES

None

REFERENCES

1. 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-houru sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD). An update for 2015. *J Clin Sleep Med*. 2015;11(10):1199-1236.
2. Hetlioz (tasimelteon) [prescribing information]. District of Columbia, U.S.: Vanda Pharmceuticals; January 2024.
3. Hudson T and Bush B. The role of cortisol in sleep. *Natural Medicine Journal*. 2010;2(6):26-9.
4. Lockley SW, Dressman MA, Xiao C, et al. Tasimelteon treatment entrains the circadian clock and demonstrates a clinically meaningful benefit in totally blind individuals with non-24-hour circadian rhythms. Sleep Medicine. 2013;14(Suppl 1):e178.
5. Lockley SW, Dressman MA, Xiao C, et al. RESET study demonstrates that tasimelteon maintains entrainment of melatonin and cortisol in totally blind individuals with non-24-hour circadian rhythms. Poster presented at the The Endocrine Society National Meeting ENDO 2013a. San Francisco, CA; 2013b June 16. Abstract SUN-134. URL: https://endo.confex.com/endo/2013endo/webprogram/Paper7810.html. Available from Internet. Accessed 2016 June 22.
6. Sheldon SH. Medical disorders resulting in problem sleeplessness in children. UpToDate. Available at: www.uptodate.com. Accessed 8 August 2023.
7. Zee PC, Attarian H, and Videnovic A. Circadian rhythm abnormalities. *Continuum*. 2013;132-47.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, updated specialist language to say Hetlioz is prescribed by or in consultation with a sleep specialist. Updated previous trial language to say "inadequate response, adverse reaction, or contraindication to." Updated criteria for SMS for members 16 years of age or older to allow for approval of the liquid if the provider indicates that the liquid is medically necessary for the member. Updated limitations section of the MNG to include language for requests for brand name products with AB-rated generics, as Hetlioz capsule is now available generically. Updated reauthorization criteria to require documentation that the member continues to have a positive response to therapy.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: No changes.

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.

Provider Services