Pharmacy Medical Necessity Guidelines: Hetlioz® (tasimelteon)

Effective: May 12, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

Non-24-hour sleep-wake disorder (N24) is a serious circadian rhythm sleep disorder. The development of this disorder is due to light signals not reaching the suprachiasmatic nucleus in totally blind individuals. Individuals with N24 exhibit sleep-wake patterns that show a progressive delay (typical) or advance, depending upon the period length of their endogenous circadian rhythms. Early symptoms of N24 include periodic night-time insomnia and excessive daytime sleepiness. Most patients with N24 are totally blind, but the disorder can also occur among sighted individuals.

Hetlioz (tasimelteon) is a novel circadian regulator with selective agonist activity for melatonin MT1 and MT2 receptors. These receptors are thought to be involved in the control of circadian rhythms. Clinical trials evaluating the efficacy and safety of the Hetlioz (tasimelteon) included only totally blind individuals with N24.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Hetlioz (tasimelteon) is a melatonin receptor agonist to treat non-24 hour sleep-wake disorder in totally blind individuals.

COVERAGE GUIDELINES

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

1. Documentation the Member is totally blind

AND

2. Documented diagnosis of Non-24 sleep-wake disorder by a sleep specialist

AND

3. The Member has had an insufficient response or intolerance to melatonin and at least one additional generic medication indicated for sleep

Reauthorization:

1. Documentation the Member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with Hetlioz is medically necessary.

LIMITATIONS

1. The plan will not cover for 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. The following quantity limitation applies:

Hetlioz (tasimelteon) capsules	30 capsules 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 Pharmaceuticals; Dec 2014.
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. Zee PC, Attarian H, and Videnovic A. Circadian rhythm abnormalities. *Continuum*. 2013;132-47.

APPROVAL HISTORY

July 8, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 14, 2015: No changes
2. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
3. July 12, 2016: No changes. Effective July 12, 2016 Medical Necessity Guideline applies to Tufts Health Together.
4. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
5. July 11, 2017: No changes.
6. June 12, 2018: Effective 10/1/18, criteria was updated to require trial and failure of two *generic* medications for sleep.
7. July 10, 2018: Effective 10/1/2018, the MNG was split from Commercial and limitation section was updated to reflect only the Medicaid duration of approval.
8. June 11, 2019: Updated approval criteria to require a trial and failure with melatonin and one additional generic medication indicated for sleep. Administrative changes made to template.
9. May 12, 2020: 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