Mass General Brigham
Health Plan

Tasimelteon capsules (generic Hetlioz)
Effective 07/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Tasimelteon (generic Hetlioz) is a melatonin receptor antagonist indicated for the treatment of:

- Non-24-hour sleep-wake disorder in adults
- Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when ALL the following criteria are met:

1. Member meets ONE of the following
    a. Member is 18 years of age or older and has a diagnosis of non-24-hour sleep-wake disorder (non-24)
    b. Member 16 years of age or older and has a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
2. Requested medication is prescribed by or in consultation with a sleep specialist
3. Member has had at least a one-month trial of timed melatonin administration that resulted in a side effect, allergy, or treatment failure

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Submission of medical records (e.g., chart notes) documenting a positive response to therapy

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Tasimelteon 20mg capsule	1 capsule per day

References

1. Hetlioz (tasimelteon) [prescribing information]. Washington, DC: Vanda Pharmaceuticals; January 2024.
2. 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): e17

Review History

09/21/2015: Reviewed P&T Mtg
12/29/2015: Implementation Date
11/27/2017: Reviewed P&T Mtg
11/26/2018: Reviewed P&T Mtg
01/22/2020: Added started and stabilized criteria, added indication of non-24 hour sleep wake disorder, removed Rozerem trial
07/21/2021: Reviewed and Updated July P&T; Added Hetlioz LQ and SMS nighttime sleeps disturbances for Hetlioz. Effective 08/01/2021.
06/11/2025: Reviewed at June P&T. No changes. Effective 07/01/2025.
04/15/2025 – Reviewed and updated at April P&T. Removed Hetlioz LQ from the policy, as agent is moving to nonformulary status. Updated policy to reflect generic availability of Hetlioz capsule. Effective 07/01/2026.