Mass General Brigham
Health Plan

Hetlioz® (tasimelteon tablets)
Hetlioz LQ® (tasimelteon oral suspension)
Effective 07/01/2025

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Hetlioz is a melatonin receptor antagonist.
Hetlioz capsules are 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

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.

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication 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:

Hetlioz

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. Prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist
3. Pember has had at least a one-month trial of timed melatonin administration that resulted in a side effect, allergy, or treatment failure

Hetlioz LQ:

1. Member has a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
2. Member is between age 3 years and 15 years old
3. Prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist
4. 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. Documentation is submitted indicating 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
Hetlioz 20mg capsule	1 capsule per day
Hetlioz LQ 4 mg/mL suspension	5 mL 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.