Mass General Brigham
Health Plan

Hetlioz® (tasimelteon tablets)
Hetlioz LQ® (tasimelteon oral suspension)
Effective 08/01/2021

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 an agonist of melatonin receptors which induces sleepiness and influences regulation of circadian rhythms.

Coverage Guidelines
Authorization may be reviewed for members new to the plan 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, and documentation is provided:

Hetlioz
Authorization may be reviewed for members new to the plan 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, and documentation is provided:

1. The member meets ONE of the following
   a. The member is at least 18 years old and has a diagnosis of non-24-hour sleep-wake disorder (non-24)
   b. The member is at least 16 and has a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
2. The prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist
3. The member 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. The member has a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
2. The member is between age 3 years and 15 years old
3. The prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist
4. The 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

Reauthorization will be granted if 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:

Hetlioz 20mg	30 capsules per 30 days
Hetlioz LQ 4 mg/mL suspension	150 mL per 30 days

References

1. Hetlioz (tasimelteon) [prescribing information]. Washington, DC: Vanda Pharmaceuticals; October 2019.
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
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-houru sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm

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.