

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

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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.

