Clinical Policy Title:	tasimelteon
Policy Number:	RxA.390
Drug(s) Applied:	Hetlioz®, Hetlioz LQ™
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-24-Hour Sleep-Wake Disorder (must meet all)**:**

1. Diagnosis of non-24-hour sleep-wake disorder;
2. Request is for Hetlioz® capsules;
3. Trail and failure of melatonin, unless contraindicated or clinically significant adverse effects are experienced;
4. Member is completely blind (no light perception).

Approval duration

All Lines of Business (except Medicare): 12 months

B. Night-time sleep disturbances in Smith-Magenis Syndrome (must meet all)**:**

1. Diagnosis of night-time sleep disturbances in Smith-Magenis Syndrome (SMS);
2. One of the following (a or b):
   a. Request is for Hetlioz® capsule and age is ≥ 16 years;
   b. Request is for Hetlioz LQ™ oral suspension and age is 3 to 15 years;
3. Trail and failure of melatonin, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. Auger RR, Burgess HJ, Emens JS, Deriy LV, Thomas SM, and Sharkey KM. 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-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD) – An Update for 2015. An American Academy of Sleep Medicine Clinical

Practice Guideline. J Clin Sleep Med. 2015; 11(10): 1199-1236. Available at: https://jcsm.aasm.org/doi/10.5664/jcsm.5100. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was updated to "All lines of business". 3. Clinical policy was updated: Approval duration was updated from length of benefit to 12 months for Continued Approval Criteria. Initial Approval Criteria was updated. 4. Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy".	06/19/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy drugs applied was updated to include “Hetlioz LQ™.” 2. Initial Approval Criteria I.A.3 was updated to include “Member should be age ≥ 18 years …” 3. Initial Approval Criteria I.B was updated to include new indication “Night-time sleep disturbances in Smith-Magenis Syndrome…” 4. Continued Therapy Approval Criteria II.A was updated from “Non-24 Hour Sleep Wake Disorder” to “All Indications in Section I.” 5. References were reviewed and updated.	05/31/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.5 updated to remove ramelteon (Rozerem®). 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	03/23/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to include new requesting criteria Request is	04/20/2023	07/13/2023

for Hetlioz® capsules. 2. Initial Approval Criteria, I.A.4 and I.B.4: Updated to remove prior concurrent therapy criteria Member is not taking strong CYP1A2 inhibitors (e.g., fluvoxamine) or CYP3A4 inducers (e.g., rifampin). 3. Initial Approval Criteria, I.A & I.B: Updated Approval duration from 6 to 12 months for Commercial and Medicaid. 4. Initial approval criteria I.B.6 updated from Dose does not exceed 20 mg (1 capsule) per day to Dose does not exceed one of the following (a or b): a. Hetlioz: Dose does not exceed 20 mg per day. b. Hetlioz LQ, one of the following (i or ii): i. Weight ≤ 28 kg: 0.7 mg per kg per day; ii. Weight > 28 kg: 20 mg per day; 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024