RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	tasimelteon
Policy Number:	RxA.390
Drug(s) Applied:	Hetlioz®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Tasimelteon (Hetlioz®) is a melatonin receptor agonist. It is indicated for treatment of non-24-hour sleep-wake disorder (non-24).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tasimelteon (Hetlioz®)	Non-24-hr-sleep-wake disorder	20 mg PO once daily at the same time each night before bedtime	20 mg/day

Dosage Forms

- Capsule: 20 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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. Prescribed by or in consultation with a specialist in sleep disorders;
3. Member is not taking strong CYP1A2 inhibitors (e.g., fluvoxamine) or CYP3A4 inducers (e.g., rifampin).
4. Failure of melatonin and ramelteon (Rozerem®), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for ramelteon*
5. Member is completely blind (no light perception);
6. Dose does not exceed 20 mg (1 capsule) per day.

Approval duration:
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 20 mg (1 capsule) per day.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

I. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
Non-24: Non-24-Hour Sleep-Wake Disorder

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
melatonin	5 to 10 mg PO QHS	N/A
Rozerem (ramelteon)	8 mg PO QHS	8 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

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References

1. Hetlioz® Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc. October 2019 . Available at: www.hetlioz.com. Accessed June 18, 2020 .
2. 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. Accessed June 19,2020.
3. Williams WP , McLin DE , Dressman MA, Neubauer DN. Comparative Review of Approved Melatonin Agonists for the Treatment of Circadian Rhythm Sleep-Wake Disorders. Pharmacotherapy. 2016 Sep;36(9):1028-41. Accessed June 19,2020.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed June 19, 2020.
5. Tasimelteon, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed June 18, 2020.
6. Williams WP, Mclin DE, Dressman MA, Neubauer DN. Comparative Review of Approved Melatonin Agonists for the Treatment of Circadian Rhythm Sleep-Wake Disorders. Pharmacotherapy. 2016;36(9):1028-41. Accessed June 19, 2020

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. 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" 3. APPENDIX A was updated: "Non-24: Non-24-Hour Sleep-Wake Disorder" 4. APPENDIX D was updated: "Non-24 is a chronic circadian rhythm disorder that that often occurs totally blind individuals with decreased or no light perception". 5. References were updated	06/19/2020	09/14/2020