



MASSACHUSETTS

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Pharmacy Medical Policy **HETLIOZ™ (tasimelteon)**

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Policy Number: 697

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy [#621A](#).

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Step Therapy <input checked="" type="checkbox"/> Quality Care Dosing		Pharmacy Operations: Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy last updated 7/1/2023
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> MED	To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.
Policy applies to Commercial Members: <ul style="list-style-type: none"> Managed Care (HMO and POS), PPO and Indemnity MEDEX with Rx plan Managed Major Medical with Custom BCBSMA Formulary Comprehensive Managed Major Medical with Custom BCBSMA Formulary Managed Blue for Seniors with Custom BCBSMA Formulary 		Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043 Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Drug	Formulary Information
	Standard
	Formulary Status
Hetlioz™ (tasimelteon)	PA Required
tasimelteon	PA Required

We may cover tasimelteon for the treatment Non 24 sleep-wake disorder when **all** of the following criteria are met¹:

- Member is 18 years of age or older; AND
- Member is totally blind and has no perception of light; AND
- Documented diagnosis of Non 24 sleep-wake disorder, AND
- Prescribed by a board certified or board eligible Sleep Specialist, AND
- Documented 6 months treatment failure with (Over The Counter) non-prescription melatonin.

We may cover **Hetlioz™ (tasimelteon)** with a trial and failure with tasimelteon.

We may cover Hetlioz™ (tasimelteon) or Hetlioz™ LQ (tasimelteon) for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) when **all** of the following criteria are met:

- Member is 3 years of age or older (LQ is a suspension); **AND**
- Confirmation of the microdeletions (17p11.2) or mutations of *RAI1*

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We do not cover **Hetlioz™ (tasimelteon)** for other conditions not listed above.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's

contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Policy History

Date	Action
7/2023	Reformatted Policy.
2/2023	Updated to add tasimelteon to the policy.
1/2021	Updated to add new indication to Hetlioz™.
6/2017	Updated address for Pharmacy Operations.
10/2014	Implemented new policy for Hetlioz.

References

1. Hetlioz™ [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.: Jan 2014
2. Morgenthaler TI, et.al; Standards of Practice Committee of the AASM. Practice Parameters for the Clinical Evaluation and Treatment of Circadian Rhythm Sleep Disorders. *SLEEP* 2007;30(11):1445-1459

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>