

**Pharmacy Policy**

---

**Insomnia Agents**

**Policy Number:** 9.211

**Version Number:** 2.0

**Version Effective Date:** 6/1/2021

Product Applicability <input type="checkbox"/> <b>All Plan+ Products</b>	
<p><b>Well Sense Health Plan</b></p> <input type="checkbox"/> New Hampshire Medicaid	<p><b>Boston Medical Center HealthNet Plan</b></p> <input type="checkbox"/> MassHealth- MCO <input type="checkbox"/> MassHealth- ACO <input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

---

**Products Affected:**

- **Hetlioz (tasimelteon)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All medically excepted indications unless otherwise excluded
<b>Required Medical Information</b>	1. Member is totally blind; <b>AND</b> 2. A diagnosis of non-24 hour sleep-wake disorder; <b>AND</b> 3. The member had had an insufficient response to melatonin; <b>AND</b> 4. Absence of medications that interact with Hetlioz (e.g., fluvoxamine, rifampin)
<b>Prescriber Restriction</b>	Medication is prescribed by a sleep specialist or neurologist

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

<b>Coverage Duration</b>	12 months
<b>Other criteria</b>	Reauthorization <ol style="list-style-type: none"> <li>1. Clinical improvement of insomnia (such as improved sleep at night and improved daytime function) without major side effects; AND</li> <li>2. Attestation that the member has had an office visit and been re-assessed for non-24 hour sleep-wake disorder within the past year, and continued therapy with Hetlioz is medically necessary.</li> </ol>

### Clinical Background Information and References

1. Bonnet MH, Arand DL. "Treatment of Insomnia". UpToDate®. Accessed April 2016; available from: <http://www.uptodate.com>
2. FDA News Release: FDA approved Hetlioz: first treatment for non-24 hour sleep-wake disorder in blind individuals. Last updated 2/3/2014.
3. Dhillon S, Clarke M. Tasimelteon: first global approval. *Drugs*. 2014;74:505-511.
4. Product Information: Hetlioz™, tasimelteon. Vanda Pharmaceuticals, Inc. Washington, D.C., January 2014.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.114 Insomnia Agents Policy retired, new policy created.	1/1/2021	P&T Committee
2/11/2021	P&T annual review. No Changes.	2/12/2021	P&T Committee

### Next Review Date

2/2022

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

## Other Applicable Policies

---

## Reference to Applicable Laws and Regulations, If Any

---

### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

<sup>\*</sup> *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.