BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Insomnia Agents

Policy Number: 9.211
Version Number: 2.0
Version Effective Date: 6/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

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

Prior Authorization Policy

Products Affected:

- **Belsomra (suvorexant)**
- **DayVigo (lemborexant)**
- **Edluar (zolpidem tartrate sublingual)**
- **Hetlioz (tasimelteon)**
- **ramelteon**
- **Silenor (doxepin)**
- **zolpidem SL**
- **Zolpimist (zolpidem tartrate oral spray)**

**Additional restrictions for members less than 6 years and multiple BH medications for members less than 18 years (MH only)*

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

Covered Use	All medically excepted indications unless otherwise excluded
Exclusion	None

[+] *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.

Criteria	
Required Medical Information	**Belsomra, DayVigo** 1. An inadequate response or intolerance to a trial of zolpidem IR/ER, zaleplon and eszopiclone; AND 2. For Belsomra: an inadequate response, intolerance, or contraindication to DayVigo. **Ramelteon** 1. An inadequate response or intolerance to a trial of zolpidem IR/ER, zaleplon and eszopiclone; OR 2. For ramelteon, prescriber attestation member has a history of or potential for substance abuse **Silenor (doxepin 3mg and 6mg)** 1. An inadequate response or intolerance to a trial of zolpidem IR/ER, zaleplon and eszopiclone; AND 2. An intolerance to a trial of liquid doxepin **Edluar, Zolpimist** 1. Swallowing difficulties due to a clinical condition; AND 2. An inadequate response to a trial of Zolpimist® (for Edluar® requests only) **zolpidem SL** 1. A diagnosis of insomnia characterized by middle-of-the-night awakening followed by difficulty returning to sleep; AND 2. An intolerance to a trial of zolpidem IR/ER; AND 3. An inadequate response to a trial of either zaleplon or eszopiclone **Hetlioz** 1. Member is totally blind; AND 2. A diagnosis of non-24 hour sleep-wake disorder; AND 3. The member has had an insufficient response to melatonin; AND 4. Absence of medications that interact with Hetlioz (e.g., fluvoxamine, rifampin)
Age Restrictions	None
Prescriber Restriction	Hetlioz: Medication is prescribed by a sleep specialist or neurologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Clinical improvement of insomnia (such as improved sleep at night and improved daytime function) without major side effects; AND 2. Member is receiving cognitive behavioral therapy (such as sleep hygiene, relaxation, stimulation control, etc.) and has failed dose taper and/or discontinuation of the requested insomnia medication.

***Additional criteria for members under 18 years of age**

Medication	Prior Authorization Criteria (MassHealth Members < 18 years old need to meet the approval criteria under the PBHMI policy in addition to the drug specific criteria listed above)
	Initial Therapy
PBHMI: Hypnotic or hypnotic benzodiazepine for < 6 years old	Refer to policy 9.500 (Pediatric Behavioral Health Medication Initiative) for pediatric approval criteria
PBHMI: Any combination of 4 or more BH medications: A. Treatment regimen includes two or fewer mood stabilizers; OR B. Treatment regimen includes three or more mood stabilizers	Refer to policy 9.500 (Pediatric Behavioral Health Medication Initiative) for pediatric approval criteria

Clinical Background Information and References

1. NIH State-of-the-Science Consensus Statement on Manifestations and Management of Chronic Insomnia in Adults. Vol. 22, Number 2; June 13-15, 2005.
2. Product Information: Rozerem®, ramelteon. Takeda Pharmaceuticals America, Inc., Deerfield, IL, 2006.
3. Product Information: Ambien CR®, zolpidem tartrate extended-release tablets. Sanofi-Aventis U.S. LLC, Bridgewater, NJ, 2007.
4. Product Information: Lunesta®, eszopiclone. Sepracor Inc, Marlborough, MA, 2006.
5. Product Information: Silenor®, doxepin. Somaxon Pharmaceuticals, Inc. San Diego, CA. Accessed on May 1, 2012
6. Product Information: Edluar, solpidem sublingual tablets. Meda Pharmaceuticals Inc. Sommerset, NJ. Accessed on May 1, 2012.
7. Product Information: Intermezzo, zolpidem sublingual tablets. Prudue Pharma L.P. Stamford, CT, December 2012.
8. Bonnet MH, Arand DL. "Treatment of Insomnia". UpToDate®. Accessed April 2016; available from: http://www.uptodate.com

9. FDA News Release: FDA approved Hetlioz: first treatment for non-24 hour sleep-wake disorder in blind individuals. Last updated 2/3/2014.
10. Dhillon S, Clarke M. Tasimelteon: first global approval. *Drugs*. 2014;74:505-511.
11. Product Information: Hetlioz™, tasimelteon. Vanda Pharmaceuticals, Inc. Washington, D.C., January 2014.
12. Product Information: Belsomra®. Merck & Co., Inc. Whitehouse Station, NJ, August 2014
13. Schutte-Rodin S, et al. Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults. J Clin Sleep Med. 2008 Oct 15;4(5):487-504
14. DayVigo (lemborexant) [prescribing information]. Woodcliff Lake, NJ: Eisai, Inc. April 2020.

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. Add DayVigo to policy and prefer it over Belsomra	6/1/2021	P&T Committee

Next Review Date

2/2022

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.