BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Narcolepsy

Policy Number: 9.208
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:

- **Armodafinil (Nuvigil)**
- **Modafinil (Provigil)**
- **Wakix (pitolisant)**
- **Xyrem (sodium oxybate)**
- **Xywav (oxybate salts)**
- **Sunosi (solriamfetol)**

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

Covered Use	All medically accepted indications unless otherwise excluded
Exclusion Criteria	Wakix • End stage renal disease, hepatic impairment, and/or QT prolongation Xyrem, Xywav

[+] *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.

	• Concurrent use of CNS depressants (e.g. ethanol, sedative hypnotics, anxiolytics, barbiturates, benzodiazepines)
Required Medical Information	**Armodafinil** 1. Excessive daytime sleepiness associated with a confirmed diagnosis of narcolepsy; ***OR*** 2. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea in which CPAP is concurrently being utilized; ***OR*** 3. Fatigue associated with multiple sclerosis that has not responded to non-pharmacologic therapies, and an inadequate response or contraindication to either amantadine or a CNS stimulant (e.g. methylphenidate or amphetamine salts) **Modafinil** 1. Diagnosis of one of the following: a. Excessive daytime sleepiness associated with a confirmed diagnosis of narcolepsy; ***OR*** b. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea in which CPAP is concurrently being utilized; ***OR*** c. Fatigue associated with multiple sclerosis that has not responded to non-pharmacologic therapies, and an inadequate response or contraindication to either amantadine or a CNS stimulant (e.g. methylphenidate or amphetamine salts); ***AND*** 2. An inadequate response, intolerance or contraindication to armodafinil **Sunosi** 1. Excessive daytime sleepiness associated with narcolepsy; ***AND*** a. An inadequate response, adverse reaction, or contraindication to a CNS stimulant agent (e.g. methylphenidate or amphetamine salts); ***AND*** b. An inadequate response, adverse reaction, or contraindication to modafinil or armodafinil; ***OR*** 2. Excessive daytime sleepiness associated with obstructive sleep apnea in which CPAP is concurrently being utilized; ***AND*** a. An inadequate response, adverse reaction, or contraindication to modafinil or armodafinil **Wakix** 1. Excessive daytime sleepiness associated with narcolepsy; ***AND***

	a. An inadequate response, adverse reaction, or contraindication to a CNS stimulant agent (e.g. methylphenidate or amphetamine salts); ***AND*** b. An inadequate response, adverse reaction, or contraindication to modafinil or armodafinil; ***AND*** c. An inadequate response, adverse reaction, or contraindication to Sunosi; ***OR*** 2. Narcolepsy with cataplexy ; ***AND*** a. An inadequate response, adverse reaction, or contraindication to two of the following: a tricyclic antidepressant, atomoxetine, SSRI, venlafaxine **Xyrem, Xywav** 1. Narcolepsy with cataplexy; ***AND*** a. An inadequate response, intolerance or contraindication to two of the following: a tricyclic antidepressant, atomoxetine, SSRI, venlafaxine; ***AND*** b. For Xyrem only: an inadequate response, intolerance or contraindication to Xywav; ***OR*** 2. Excessive daytime sleepiness associated with narcolepsy; ***AND*** a. An inadequate response, adverse reaction, or contraindication to a CNS stimulant agent (e.g. methylphenidate or amphetamine salts); ***AND*** b. An inadequate response, adverse reaction, or contraindication to modafinil or armodafinil; ***AND*** c. An inadequate response, adverse reaction, or contraindication to Sunosi; ***AND*** d. For Xyrem only: an inadequate response, intolerance or contraindication to Xywav
Age Restrictions	Armodafinil, modafinil, Sunosi, Wakix: 18 years and older Xyrem, Xywav: 7 years and older
Prescriber Restriction	Wakix, Xyrem, Xywav, and Sunosi: Prescribed by or in collaboration with a sleep disorder specialist, psychiatrist, or neurologist
Coverage Duration	12 months
Other criteria	<u>Reauthorization:</u> Provider attestation that the member has had an office visit and has been re-assessed for the condition within the past year, and continued therapy with this medication is considered medically necessary

Clinical Background Information and References

1. Product Information, Provigil®, modafinil. Cephalon, Inc., Frazer, PA, January 2015
2. US Modafinil in Narcolepsy Multicenter Study Group. Randomized trial of modafinil as a treatment for the excessive daytime somnolence of narcolepsy. Neurology. 2000;54:1166-1175.
3. Pack AI, Black JE, Schwartz JRL, Matheson JK, for the U.S. Modafinil in Obstructive Sleep Apnea Study Group. Modafinil as adjunct therapy for daytime sleepiness in obstructive sleep apnea. Am J Respir Crit Care Med. 2001;164:1675-1681.
4. Black JE, Hirshkowitz M. Modafinil for treatment of residual excessive sleepiness in nasal continuous positive airway pressure-treated obstructive sleep apnea/hypopnea syndrome. Sleep. 2005;287:464-471.
5. Product Information: Nuvigil®, armodafinil. Cephalon, Inc., Frazer, PA, April 2015.
6. Michael J Olek, DO, editor Francisco Gonsalez-Scarano, MD, John Dashe, MD, PhD. Comorbid problems associated with multiple sclerosis in adults. UpToDate [database on the Internet]. Accessed April 2014
7. Krull KR. UpToDate. Pharmacology of drugs used to treat attention deficit hyperactivity disorder in children and adolescents. Accessed April 2014
8. Atwood C. Pharmacologic treatment of obstructive sleep apnea in adults. UpToDate. Updated March 2016. Accessed April 2016
9. Carlton R, et al. Healthcare Costs Among Patients with Excessive Sleepiness Associated with Obstructive Sleep Apnea, Shift Work Disorder, or Narcolepsy. Am Health Drug Benefits. 2014 Sep; 7(6): 334–340
10. Xywav (calcium, magnesium, potassium, and sodium oxybates solution) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. October 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**

Policy Revisions History			
12/1/2020	9.101 Armodafinil-Modafinil Policy retired, new policy created, renamed Narcolepsy Policy	1/1/2021	P&T Committee
2/11/2021	P&T annual review. Added Xywav to policy and preferred it over Xyrem; added narcolepsy with cataplexy diagnosis to Wakix; updated age restrictions.	6/1/2021	P&T Committee

Next Review Date

2/2022

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.