BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Savella

Policy Number: 9.202
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:

- **Savella (milnacipran)**

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

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	1. A diagnosis of fibromyalgia; AND 2. Inadequate response, adverse reaction, or contraindication to gabapentin; AND 3. An inadequate response, intolerance or contraindication to a trial of a tricyclic antidepressant AND

[+] *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.

	4. An inadequate response, intolerance or contraindication to a trial of duloxetine.
Age Restriction	18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a rheumatologist, physiatrist, pain management specialist or Neurologist
Coverage Duration	1 year
Quantity Limit	Savella® 4-week titration pack: 1 titration pack Savella tablets: 2 per day

Clinical Background Information and References

1. Product Information. Savella (milnacipran HCL). Forest Pharmaceuticals, Inc. St. Louis, MO. 63045. December 2016.
2. Goldenberg DL. Initial treatment of fibromyalgia in adults. UptoDate. Last updated January 2021. Accessed January 2021.
3. Goldberg DL. Treatment of fibromyalgia in adults not responsive to initial therapies. UpToDate. Last updated January 2021. Accessed January 2021.
4. Goldenberg DL, Burckhardt C, Crofford L. Management of fibromyalgia syndrome. JAMA. 2004. Nov; 292(19):2388-95.
5. Carville SF, Arendt-Nielsen S, Bliddal H, et al. EULAR evidence-based recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2008 Apr; 67(4):536-41.
6. Wolfe F, Clauw DJ, Fitzcharles M, et al. The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity. Arthritis Care Res. 2010 May;62(5):600-610.
7. National Guideline Clearinghouse (NGC). Guideline summary: Management of fibromyalgia syndrome in adults. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); [cited 2013 Aug 27]. Available: http://www.guideline.gov.
8. Hauser W, Wolfe F, Tolle T, Uceyler N, Sommer C. The role of antidepressants in the management of fibromyalgia syndrome: a systematic review and meta-analysis. *CNS Drugs*. 2012;26(4):297-307.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
9/10/2020	P&T Annual review. Criteria changes include addition of gabapentin as additional trial failure and 1 year approval duration. Retired policy 9.024 and created a separate policy for each applicable line of business.	1/1/2021	(P&T Committee
2/11/2021	P&T annual review. No criteria changes recommended.	6/1/2021	Pharmacy & Therapeutics (P&T) Committee

Next Review Date

2/2022

Other Applicable Policies

9.080 Non Preferred Policy
9.015 Quantity Limitation Policy

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.