

Pharmacy Policy

Savella

Policy Number: 9.202

Version Number: 2.0

Version Effective Date: 6/1/2021

Product Applicability <input type="checkbox"/> All Plan⁺ Products	
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<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:

- **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	<ol style="list-style-type: none"> 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

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	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

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. Goldenberg DL, Burckhardt C, Crofford L. Management of fibromyalgia syndrome. JAMA. 2004. Nov; 292(19):2388-95.
4. Goldberg DL. Treatment of fibromyalgia in adults not responsive to initial therapies. UpToDate. Last updated January 2021. Accessed January 2021.
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

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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
02/11/2021	P&T annual review. No criteria changes recommended.	6/1/2021	P&T Committee

Next Review Date

February 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

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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.

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