Pharmacy Medical Necessity Guidelines:
Savella® (milnacipran)

Effective: September 15, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Savella (milnacipran) is indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

COVERAGE GUIDELINES

The plan may authorize coverage of Savella (milnacipran) for Members when the following criteria are met and limitations do not apply:

1. The Member has a diagnosis of fibromyalgia

AND

2. One of the following:
   a) The Member has been stable on milnacipran for at least two months

   OR

   b) The Member was recently started on milnacipran in an acute care setting

   OR

   c) The Member has tried and failed therapy with at least two generic agents, such as gabapentin, pregabalin, or antidepressant medications (tricyclic antidepressant, selective serotonin reuptake inhibitor, serotonin-norepinephrine reuptake inhibitor)

LIMITATIONS

1. The following quantity limit applies:

Savella (milnacipran HCl) tablets	60 capsules per 30 days
Savella titration pack	1 pack per lifetime

CODES

None

REFERENCES

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2. Arnold LM, Rosen A, Pritchett YL et al. A randomized, double-blind, placebo-controlled trial of duloxetine in the treatment of women with fibromyalgia with or without major depressive disorder. *Pain* 2005; 119:5–15.
3. Crofford LJ, et al. Fibromyalgia relapse evaluation and efficacy for durability of meaningful relief (FREEDOM): a 6-month, double-blind, placebo-controlled trial with pregabalin. *Pain* 2008; 136:419-431.
4. Goldenberg DL. Treatment of fibromyalgia in adults not responsive to initial therapies. UpToDate. Available at: www.uptodate.com. Accessed 8 August 2023.
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6. Macfarlan GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2016 doi: 10.1136/annrheumdis-2016-209724.
7. Mease PJ, et al. The efficacy and Safety of Milnacipran for Treatment of Fibromyalgia. A Randomized, Double-blind, Placebo-controlled Trial. *J Rheumatol* 2009; 36:398-409.
8. Mease PJ, et al. a randomized, double-blind, placebo-controlled, phase III trial of pregabalin in the treatment of patients with fibromyalgia. *J Rheumatol* 2008; 35: 502-514

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10. Savella (milnacipran) [package insert]. Madison, NJ: Allergan USA, Inc; December 2022.
11. Weir PT, et al. The Incidence of Fibromyalgia and its Associated Comorbidities: A Population Based Restrospective Cohort Study Based on International Classification of Diseases, 9th Revision Codes. *J Clin Rheumatol*. 2006:12(3):124-128.
12. Macfarlan GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2016 doi: 10.1136/annrheumdis-2016-209724.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative change to fax number
3. September 9, 2025: No changes
4. September 15, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services