Pharmacy Medical Necessity Guidelines: Savella® (milnacipran)

Effective: May 12, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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.

Milnacipran hydrochloride is a selective norepinephrine and serotonin reuptake inhibitor; it inhibits norepinephrine uptake with greater potency than serotonin. It is not used to treat depression. It delivers simultaneous improvements on three measures of fibromyalgia:

- Pain reduction
- Improvement in patient global fibromyalgia assessment
- Improvement in physical function

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 gabapentin

   OR

   d) The Member tried and failed therapy with at least two alternative antidepressant medications from at least one of the following classes: tricyclic antidepressant, selective-serotonin reuptake inhibitor, or serotonin-norepinephrine reuptake inhibitor

LIMITATIONS

1. The following quantity limit applies:

Savella (milnacipran HCl) tablets	60 capsules per 30 days

CODES

None

REFERENCES

1. Savella [package insert]. Irvine, CA: Forest Pharmaceuticals; December 2017.

2. https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 2009].
3. Paris BL, et al. In vitro inhibition and induction of human liver cytochrome P450 (CYP) enzymes by milnacipran. *Drug Metab Dispos.* 2009: Jul 16; 1-33.
4. Berger A, et al. Characteristics and Healthcare Costs of Patients with Fibromyalgia Syndrome. *Int J Clin Pract*. 2007; 61(9): 1498-1508.
5. American College of Rheumatology (ACR). Fibromyalgia. 2006 http://www.rheumatology.org/publications/classification/fibromyalgia/fibro.asp. Accessed July 2009
6. Abeles M, et al. Update on Fibromyalgia Therapy. *Am J Med.* 2008 Jul;121(7):555-61.
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. Goldberg D, et al. One-year durability of response to milnacipran treatment for fibromyalgia syndrome: results of a randomized, double-blind, montherapy extension study. 24th Annual Meeting of the American Academy of Pain Medicine; 2008; Orlando, Florida. Abstract 172.
9. 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.
10. Russell IJ, Mease PJ, Smith TR et al. Efficacy and safety of duloxetine for treatment of fibromyalgia in patients with or without major depressive disorder: results from a 6-month, randomized, double-blind, placebo-controlled, fixed-dose trial. *Pain* 2008; 136:432–444.
11. 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.
12. 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
13. 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.
14. Goldenberg DI. Treatment of fibromyalgia in adults not responsive to initial therapies. UpToDate. Accessed 28 May 2019.
15. 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 15, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. October 20, 2011: No changes
2. August 12, 2014: No changes
3. August 11, 2015: No changes
4. January 1, 2016: Administrative change to rebranded template
5. August 9, 2016: No changes
6. May 9, 2017: Administrative update, adding Tufts Health RITogether to the template
7. August 8, 2017: No changes
8. August 7, 2018: No changes.
9. June 11, 2019: Administrative changes made to template.
10. May 12, 2020: 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.