Pharmacy Medical Necessity Guidelines: Savella® (milnacipran)

Effective: November 10, 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

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan using the Universal Pharmacy Medical Review Request Form for members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
gabapentin	Covered	Covered
Step-2		
Savella (milnacipran)	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: The plan may cover Step 2 medications if the following criteria are met:

a) The Member has had a trial of one (1) Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

1. The Member has had a trial of a Step-1, Step-2 medication as evidenced by physician's documented use, excluding the use of samples

OR

2. The plan may authorize coverage of Savella (milnacipran) if all of the following criteria are met:
   a) The Member has a documented diagnosis of fibromyalgia

AND

b) The Member has a physician documented a trial and failure with one, or contraindication or intolerance to all of the following medications: gabapentin, Cymbalta (duloxetine), or Lyrica (pregabalin)

LIMITATIONS

1. Previous use of samples or vouchers/coupons for Savella (milnacipran) will not be considered for authorization.
2. Medications on Step-2 are not covered unless the above step therapy criteria are met.
3. A quantity limitation of 180 units per 90 days applies to Savella (milnacipran).

CODES

None

REFERENCES

1. Arnold LM, et al. Gabapentin in the treatment of fibromyalgia: a randomized, double-blind, placebo-controlled, multicenter trial. *Arthritis Rheum.* 2007;56(4):1336-44.
2. Arnold LM, Gendreau RM, Palmer RH, et al. Efficacy and safety of milnacipran 100mg/day in patients with fibromyalgia: results of a randomized, double-blind, placebo-controlled trial. *Arthritis Rheum*. 2010 Sep;62(9):2745-56.
3. Clauw DJ, Mease P, Palmer RH, et al. Milnacipran for the treatment of fibromyalgia in adults: a 15-week, multicenter, randomized, double-blind, placebo-controlled, multiple-dose clinical trial. *Clin Ther.* 2008 Nov;30(11):1988-2004.
4. Kranzler JD, Gendreau RM. Role and rationale for the use of milnacipran in the management of fibromyalgia. *Neuropsychiatr Dis Treat*. 2010 May;25(6):197-208.
5. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Gabapentin shown effective for fibromyalgia pain. 2007 June. NIAMS Web site. URL: niams.nih.gov/ne/press/2007/06_11.htm. Accessed 2016 July 21.
6. Savella (milnacipran HCl) [package insert]. Irvine, CA: Allergan USA, Inc.; June 2019.

APPROVAL HISTORY

September 8, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- September 14, 2010: No changes
- September 13, 2011: No changes
- September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs
- June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
- September 11, 2012: No changes
- August 6, 2013: No changes
- October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
- April 1, 2014: Administrative update: Removed language pertaining to the Generic Focused Formulary and added EHB MA/RI Formulary.
- August 12, 2014: No changes
- August 11, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- August 9, 2016: Administrative update: added existing quantity limitation of 180 units/90 days into the Limitations section to be in line with the Medical Necessity Guideline template.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- August 8, 2017: No changes
- August 7, 2018: No changes
- November 12, 2019: Administrative update to clarify that members who do not meet the automated step therapy program criteria must provide documented diagnosis of fibromyalgia and documentation of treatment failure with one or contraindication to all of the following: gabapentin, Cymbalta (duloxetine), or Lyrica (pregabalin).
- November 10, 2020: Administrative update to the template.

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.