

## Savella (milnacipran) Policy Number: C4731-A

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/1/2012	02/27/2019	02/27/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL
NA	RxPA	Q2 2019

**PRODUCTS AFFECTED:**

Savella (milnacipran)

**DRUG CLASS:**

Fibromyalgia Agents

**ROUTE OF ADMINISTRATION:**

Oral

**PLACE OF SERVICE:**

Retail Pharmacy

**AVAILABLE DOSAGE FORMS:**

Savella tablets 12.5mg, Savella tablets 25mg, Savella tablets 50mg, Savella tablets 100mg, Savella titration pack 12.5mg, 25mg, and 50mg

**FDA-APPROVED USES:** indicated for the management of fibromyalgia

**COMPENDIAL APPROVED OFF-LABELED USES:** None

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:** fibromyalgia

**REQUIRED MEDICAL INFORMATION:**
**A. FIBROMYALGIA:**

1. Documented diagnosis for fibromyalgia evidenced by chart documentation showing a history of widespread pain involving the extremities for three months and localized areas of tenderness  
AND
2. Member has experienced a trial and failure of one formulary tricyclic antidepressant (TCA), one formulary muscle relaxant, gabapentin (an adequate trial at a therapeutic dose of 1200 to 2400mg per day), venlafaxine AND duloxetine  
AND
3. Member is not concurrently using an MAOI  
AND
4. Member does not have uncontrolled narrow-angle glaucoma

**DURATION OF APPROVAL:** Initial authorization: 6 months, Continuation of therapy: 12 months

**QUANTITY:** max dose of 100mg BID (200mg daily)

**PRESCRIBER REQUIREMENTS:** Prescribed by or in consultation with a Rheumatologist or practitioner specializing in the treatment of fibromyalgia. Submit consultation notes if applicable

**AGE RESTRICTIONS:** 18 years of age and older

**GENDER:**

Male and female

**CONTINUATION OF THERAPY:**

**A. FIBROMYALGIA:**

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance) [MOLINA MEDICAL/PHARMACY REVIEWER TO VERIFY]  
AND
2. Documentation of stabilization or improvement from Savella (milnacipran) therapy as demonstrated by a reported decrease or stabilization in widespread pain duration, intensity or occurrence

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:** All other uses of Savella (milnacipran) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Savella (milnacipran) is contraindicated in members with using monoamine oxidase inhibitors concomitantly or in close temporal proximity and use in patients with uncontrolled narrow-angle glaucoma.

Savella (milnacipran) can increase blood pressure and heart rate. Antidepressants may worsen depression and induce suicidality in certain patients during the early phases of treatment. serotonin syndrome has been reported with SNRIs and SSRIs. Concomitant use of serotonergic drugs such as triptans, tramadol, and drugs that inhibit serotonin reuptake, including Savella, is not recommended. Seizures have been reported in patients treated with Savella. Prescribe with caution in patients with a history of seizures.

**OTHER SPECIAL CONSIDERATIONS:** None

**BACKGROUND:**

Savella (milnacipran) is indicated for the management of fibromyalgia. Savella (milnacipran) is not approved for use in pediatric patients. Savella (milnacipran) is a selective norepinephrine and serotonin reuptake inhibitor that works in the management of fibromyalgia by inhibiting norepinephrine uptake with greater potency than serotonin. Savella (milnacipran) is not used for the treatment of depression. Compared to placebo, treatment with Savella (milnacipran) resulted in improvements in pain, patient global fibromyalgia assessment, and physical function scores in patients with fibromyalgia.

**APPENDIX:** 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](http://niams.nih.gov/ne/press/2007/06_11.htm).
6. Savella (milnacipran HCl) [package insert]. Irvine, CA: Allergan USA, Inc.; December 2017.