

## Savella (milnacipran)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Savella (milnacipran), FDA approved in 2009, is a serotonin norepinephrine reuptake inhibitor (SNRI) used for the management of pain caused by fibromyalgia. Fibromyalgia is a multi-symptom condition, commonly presenting as widespread chronic pain, fatigue and sleep issues. Treatment for fibromyalgia usually involves a combination of drugs (to relieve pain, improve sleep or mood) and non-drug treatments, such as cognitive behavioral therapy, relaxation therapy and aerobic exercise.

NOTE: Although Savella (milnacipran) has been used in the treatment of major depressive disorder and is approved for treating depression in some countries outside the US, this indication is not an FDA-labeled use.

### Definitions

**"Fibromyalgia"** is a multi-symptom condition, commonly presenting as widespread chronic pain, fatigue and sleep issues.

### Medical Necessity Criteria for Initial Authorization

The Plan considers **Savella (milnacipran)** medically necessary when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of fibromyalgia; **AND**
3. The member has documented trial and failure of non-pharmacologic therapy (e.g., cognitive behavioral therapy, education, exercise and other forms of physical therapy); **AND**
4. The member is unable to use or has tried and failed a minimum **ONE** (1) month trial of at least **THREE** (3) therapies, from at least **THREE** (3) of the following classes:
  - a. Cyclobenzaprine; **and/or**
  - b. Gabapentinoids (e.g., gabapentin, pregabalin); **and/or**
  - c. Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine ER); **and/or**
  - d. Tricyclic Antidepressants (e.g., amitriptyline); **AND**
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

**If the above prior authorization criteria are met, Savella (milnacipran) will be approved for 12 months.**

### Medical Necessity Criteria for Reauthorization:

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. recent chart documentation (within the last 3 months) shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** of the following:
  - a. clinical improvement in fibromyalgia symptoms (e.g. pain, fatigue, sleep, mood, function) since starting therapy; **or**
  - b. disease stability (e.g., maintenance of pain relief) since starting therapy

### Experimental or Investigational / Not Medically Necessary

Savella (milnacipran) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Aspergers Syndrome
- Autism Disorder

- Back pain
- Chronic Migraine
- Chronic Pain
- Degenerative Joint Disease
- Depression
- Idiopathic Peripheral Neuropathy
- Irritable Bowel Syndrome (IBS)
- Lower Back Pain
- Major Depressive Disorder (MDD)
- Migraine With Aura
- Migraine Without Aura
- Neuropathic Pain
- Osteoarthritis (OA)
- Rheumatoid Arthritis
- Sleep disorders and disturbances
- Systemic Lupus Erythematosus
- Vestibulodynia
- Vulvodynia

## References

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2. Goldenberg DL, Burckhardt C, Crofford L. Management of Fibromyalgia Syndrome. *JAMA.* 2004;292(19):2388-95.
3. Grubisic F. Are Serotonin and Noradrenaline Reuptake Inhibitors Effective, Tolerable, and Safe for Adults with Fibromyalgia? A Cochrane Review summary with commentary. *J Musculoskeletal Neuronal Interact.* 2018;18(4):404-406.
4. Savella (milnacipran) [prescribing information]. Madison, NJ: Allergan USA Inc; August 2023.
5. Tzadok R and Ablin JN. Current and Emerging Pharmacotherapy for Fibromyalgia. *Pain Research and Management*, vol. 2020, Article ID 6541798, 9 pages, 2020. <https://doi.org/10.1155/2020/6541798>

## Clinical Guideline Revision / History Information

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