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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Neuromuscular Agents	**Original Policy Date:**	May 26, 2017
Subject:	Savella	**Page:**	1 of 4

Last Review Date: September 6, 2024

Savella

Description

Savella (milnacipran)

Background
Savella (milnacipran) is an agent used in the treatment of fibromyalgia. Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. Researchers believe that fibromyalgia amplifies painful sensations by affecting the way your brain processes pain signals. Savella is a potent inhibitor of neuronal norepinephrine and serotonin reuptake, and pharmacologic activity at these receptors is hypothesized to be associated with pain control (1).

Regulatory Status
FDA-approved indication: Savella is a selective serotonin and norepinephrine reuptake inhibitor indicated for the management of fibromyalgia (1).

Savella has boxed warning for increased risk of suicidal ideation, thinking, and behavior in adolescents and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. In clinical studies, Savella doses above 200 mg/day have not been studied (1).

The safety and effectiveness of Savella in a fibromyalgia pediatric population below the age of 18 have not been established (1).

Related policies
Lyrica, Gabapentin

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Savella may be considered **medically necessary** if the conditions indicated below are met.

Savella may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Fibromyalgia

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 18 years of age or older

Quantity

Strength	Quantity Limit
Titration Pack	1 pack per Lifetime
12.5mg, 25mg, 50mg, 100mg	200 mg per day

Prior - Approval Limits

Quantity

Strength	Quantity Limit

12.5mg, 25mg, 50mg, 100mg	Pre-PA allows for the FDA recommended maximum dosage

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Savella (milnacipran) is an agent used in the treatment of fibromyalgia. Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. Savella is a potent inhibitor of neuronal norepinephrine and serotonin reuptake, and pharmacologic activity at these receptors is hypothesized to be associated with pain control (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Savella while maintaining optimal therapeutic outcomes.

References

1. Savella [package insert]. Irvine, CA: Allergan Pharmaceuticals; May 2024.

Policy History

Date	Action
May 2017	Addition to PA
June 2017	Annual review
June 2018	Annual editorial review and reference update
October 2018	Removal of tapers from criteria
November 2018	Annual review
September 2019	Annual review
September 2020	Annual review
September 2021	Annual review
September 2022	Annual review and reference update
February 2023	Revised Pre-PA quantity chart to remove specific quantities and set all strengths at 200 mg per day
March 2023	Annual review

December 2023	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.