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# 5.75.019

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2025
<b>Subsection:</b>	Neuromuscular Agents	<b>Original Policy Date:</b>	May 26, 2017
<b>Subject:</b>	Savella	<b>Page:</b>	1 of 4

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**Last Review Date:** December 13, 2024

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## Savella

### Description

#### Savella (milnacipran)

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#### 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).

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#### Related policies

Lyrica, Gabapentin

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<b>Subject:</b>	Savella	<b>Page:</b>	2 of 4

## 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
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<b>Subsection:</b>	Neuromuscular Agents	<b>Original Policy Date:</b>	May 26, 2017
<b>Subject:</b>	Savella	<b>Page:</b>	3 of 4

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

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<b>Subject:</b>	Savella	<b>Page:</b>	4 of 4

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

## [Keywords](#)

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.**