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 indications: 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 in patients with fibromyalgia and if the conditions indicated below are met.

Savella may be considered investigational in patients that are less than 18 year of age and 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

<table>
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<tr>
<th>Strength</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>Titration Pack</td>
<td>1 pack per Lifetime</td>
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<tr>
<td>12.5mg, 25mg, 50mg</td>
<td>360 dosage units per 90 days OR</td>
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<tr>
<td>100mg</td>
<td>180 dosage units per 90 days</td>
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Maximum daily limit of any combination: 200mg

Prior - Approval Limits

Quantity
**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**


**Policy History**

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<th>Date</th>
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<tbody>
<tr>
<td>May 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>October 2018</td>
<td>Removal of tapers from criteria</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.