



RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.