

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	PAIN MANAGEMENT
BRAND NAME* (generic)	SAVELLA (milnacipran)
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization	Ref # 1345-A

*Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated

FDA-APPROVED INDICATIONS

Savella is indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- Savella is being prescribed for the management of fibromyalgia in patients 18 years of age or older

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Savella is indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.¹⁻³

Savella is a selective serotonin and norepinephrine reuptake inhibitor (SNRI), similar to some drugs used for the treatment of depression and other psychiatric disorders.¹⁻³ There is increased risk of suicidal ideation, thinking, and behavior in children, adolescents, and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. Savella is not approved for use in the treatment of major depressive disorder. Savella is not approved for use in pediatric patients. Safety and effectiveness of Savella in a fibromyalgia pediatric population below the age of 18 have not been established.¹⁻³

REFERENCES

1. Savella [package insert]. Irvine, CA: Allergan USA, Inc.; August 2016.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 2017.

Written by: UM Development (RP/NB)
Date Written: 03/2016
Revised: (RP) 09/2016; (JG) 09/2017 (no clinical changes)
Reviewed: Medical Affairs (MES) 03/2016; (LMS) 09/2016
External Review: 04/2016, 02/2017, 02/2018

CRITERIA FOR APPROVAL

1 Is Savella being prescribed for the management of fibromyalgia in a patient 18 years of age or older? Yes No

Mapping Instructions

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 12 months	Deny	Your plan covers this drug when you have fibromyalgia and you are 18 years of age or older. Your use of this drug does not meet the requirements. This is based on the information we have.