

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Savella (milnacipran)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Strength	Quantity Limit
Savella (milnacipran HCl)	12.5mg, 25mg tablets 50mg, 100mg tablets Titration pack	Limit of 10 per 30 days Limit of 60 per 30 days Limit of 1 pack per year
Quantity Supply Override: May allow a quantity of 60 tablets per 30 days of the 12.5mg or 25mg strengths if the member has renal function impairment.		

### APPROVAL CRITERIA

Requests for Savella (milnacipran) may be approved if the following criteria is met:

- I. Individual has a clinical diagnosis of Fibromyalgia(for example, based upon symptoms of widespread pain, typically reported in the muscles and joints, findings of “multiple tender points” in characteristic soft tissue locations, and any disorder that would otherwise explain the pain have been excluded); **AND**
- II. Symptoms have been present at a similar level for at least 3 months; **AND**
- III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to **two** of the following medications that are medically accepted or FDA approved for the treatment of fibromyalgia:
  - A. Tricyclic antidepressants (CF CG 2012, EULAR 2016); **OR**
  - B. Gabapentin(CFCG 2012); **OR**
  - C. Cyclobenzaprine (CF CG 2012, EULAR 2016) ; **OR**
  - D. Fluoxetine (CF CG 2012) or alternative selective serotonin reuptake inhibitor (SSRI); **OR**
  - E. Cymbalta (duloxetine)\*; **OR**
  - F. Lyrica\*

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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**Note:** Savella (milnacipran) has black box warnings for suicidality and antidepressant drugs. Savella is a SNRI, similar to some drugs used for the treatment of depression and other psychiatric disorders. Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of such drugs in an individual under the age of 24, must balance this risk with the clinical need. Individuals of all ages who are started on Savella should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Savella is not approved for use in the treatment of major depressive disorder. Savella is not approved for use in pediatric individuals.

\*Prior authorization may be required

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

#### **Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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