Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2018**
Policy Number: PA.CP.PPA.15	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Milnacipran (Savella)	**HC Approval Date:**

Type of Submission – Check all that apply:

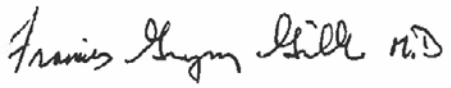
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PMN.125 Milnacipran (Savella)

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Milnacipran (Savella)

Reference Number: PA.CP.PPA.15
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Milnacipran (Savella®) is a selective serotonin and norepinephrine reuptake inhibitor (SNRI).

FDA approved indication
Savella is indicated for the management of fibromyalgia.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that Savella is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Fibromyalgia (must meet all)**:**

1. Diagnosis of fibromyalgia;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b):
   a. Failure of a 30 day trial of duloxetine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Contraindication or intolerance to duloxetine and failure of a 30 day trial of amitriptyline or cyclobenzaprine at up to maximally indicated doses, unless both agents are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 200 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Fibromyalgia (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness health benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;

3. If request is for a dose increase, new dose does not exceed 200 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
SNRI: selective serotonin and norepinephrine reuptake inhibitor

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Fibromyalgia	Based on efficacy and tolerability, dosing may be titrated according to the following schedule: *Day 1:* 12.5 mg once *Days 2-3*: 25 mg/day (12.5 mg twice daily) *Days 4-7:* 50 mg/day (25 mg twice daily) *After Day 7:* 100 mg/day (50 mg twice daily) Recommended dose is 100 mg/day (50 mg twice daily)	200 mg/day (100 mg twice daily)

VI. Product Availability

Tablets: 12.5 mg, 25 mg, 50 mg, 100 mg

VII. References

1. Savella Prescribing Information. Irvine, CA: Allergan USA, Inc.; December 2016. Available at: https://www.savella.com/. Accessed January 12, 2017.
2. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014; 311(15): 1547-1555.
3. Häuser W, Walitt B, Fitzcharles M-A, Sommer C. Review of pharmacological therapies in fibromyalgia syndrome. *Arthritis Research & Therapy*. 2014;16(1):201. doi:10.1186/ar4441.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date