Clinical Policy Title:	Milnacipran
Policy Number:	RxA.488
Drug(s) Applied:	Savella®
Original Policy Date:	03/06/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of fibromyalgia;
2. Member meets one of the following (a or b):
   a. Trial and failure of duloxetine unless contraindicated or clinically significant adverse effects are experienced;
   b. If contraindication or intolerance to duloxetine, trial and failure of amitriptyline, pregabalin, gabapentin, or cyclobenzaprine unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Kia S, Choy E. Update on Treatment Guideline in Fibromyalgia Syndrome with Focus on Pharmacology. Biomedicines. 2017 May 8;5(2):20. doi: 10.3390/biomedicines5020020. PMID: 28536363; PMCID: PMC5489806. Accessed March 29, 2024.
2. Bordeaux, B., & Lieberman, H. R. (2020). Treatment of fibromyalgia in adults. *UpToDate*. Accessed March 29, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. Commercial approval duration was updated from Length of benefit to 12 months for Initial and continued approval criteria. 4. Appendix B was updated: discontinued preferred alternative brands were removed. 5. References were updated.	09/08/2020	12/07/2020
Policy was reviewed: 1. Dosing Information was updated to add dosing regimen for patients with severe renal impairment. 2. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 3. Initial and Continued Therapy Approval Criteria was updated to remove HIM approval duration. 4. Continued Therapy Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 5. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 6. Therapeutic Alternative “cyclobenzaprine” dosing regimen is updated from ““10 mg PO every morning and 20 mg at bedtime to ”10 to 30 mg every night”. 7. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic	09/06/2021	12/07/2021

name when the drug is available by generic only". 8. References were reviewed and updated.		
Policy was reviewed: 1. Dosing Information, Dosing Regimen, Savella®: Updated renal impairment dosing information from "patients with severe renal impairment..." to Savella® should be used with caution in patients with moderate renal impairment. Added off label dose. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Appendix A: Updated to include abbreviation MDD. 4. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Wellbutrin®. 5. Appendix B, Dosing Regimen, paroxetine (Paxil®): Updated dosing information from 10 mg orally once daily to 20 mg orally once daily for indication depression. 6. Appendix B, Dosing Regimen, paroxetine SR (Paxil CR®): Updated dosing information from 12.5 mg orally once daily to 20 mg orally once daily for indication depression. 7. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Tofranil®. 8. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 9. References were reviewed and updated.	04/06/2022	07/18/2022
Policy was reviewed: 1. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative: a. Elavil® b. Flexeril® c. Wellbutrin® d. Effexor® e. Sinequan® f. Tofranil® g. Desyril®	06/29/2023	07/13/2023

2. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Removed dosing criteria.	12/6/2023	11/30/2023
Policy was reviewed. 1. Removed medication trial duration. 2. Updated medications required for trial and failure. 2. References were reviewed and updated.	3/29/2024	