Clinical Policy Title:	Milnacipran
Policy Number:	RxA.488
Drug(s) Applied:	Savella®, Milnacipran
Original Policy Date:	03/06/2020
Last Review Date:	04/10/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

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 24, 2025.
2. Bordeaux, B., & Lieberman, H. R. (2020). Treatment of fibromyalgia in adults. *UpToDate*. Accessed March 24, 2025.

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.	09/08/2020	12/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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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.		
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 name when the drug is available by generic only". 8. References were reviewed and updated.	09/06/2021	12/07/2021
Policy was reviewed: 1. Dosing Information, Dosing Regimen, Savella®: Updated renal impairment dosing information from “patients with severe renal impairment...” to Savella® should be	04/06/2022	07/18/2022

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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.		
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® 2. References were reviewed and updated.	06/29/2023	07/13/2023
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	3/29/2024	

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and failure. 2. References were reviewed and updated.		
Policy was reviewed. 1. Updated continuation of therapy language. 2. References were reviewed and updated.	03/24/2025	04/10/2025

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