

## PRIOR AUTHORIZATION POLICY

**POLICY:** Neurology – Tonmya Prior Authorization with Step Therapy Policy

- Tonmya™ (cyclobenzaprine hydrochloride sublingual tablets – Tonix Medicines)

**REVIEW DATE:** 02/04/2026; selected revision 02/11/2026

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### OVERVIEW

Tonmya, a sublingual formulation of cyclobenzaprine, is indicated for the treatment of **fibromyalgia** in adults.<sup>1</sup>

### Guidelines

Other FDA-approved therapies for fibromyalgia include the serotonin and norepinephrine reuptake inhibitors duloxetine capsules (Cymbalta®, generic) and Savella® (milnacipran tablets), as well as pregabalin capsules and oral solution (Lyrica®, generic), a gamma-aminobutyric acid analog.<sup>2-4</sup> The European League Against Rheumatism 2017 guidelines for fibromyalgia treatment recommend a multimodal and individualized approach, emphasizing non-pharmacological interventions as first-line therapy.<sup>5</sup> Tonmya and Savella are not cited in the guidelines. Duloxetine and pregabalin are cited among the recommended pharmacologic treatment options. A staged treatment model is suggested, starting with education and lifestyle changes, and escalating to more intensive therapies based on symptom severity and patient response.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tonmya. This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, the patient is directed to try 1) one of duloxetine or Savella; and 2) pregabalin (Step 1) prior to approval of Tonmya (Step 2). All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tonmya is recommended in those who meet the following criteria:

#### FDA-Approved Indication

1. **Fibromyalgia.** Approve for 1 year if the patient meets ONE of the following (A or B):
  - A) **Initial therapy.** Approve if the patient meets ALL of the following (i, ii, and iii):
    - i. Patient is  $\geq 18$  years of age and  $< 65$  years of age; AND
    - ii. Patient has tried, and, according to the prescriber, has experienced inadequate efficacy or significant intolerance with one of the following (a or b):
      - a) Duloxetine capsules (Cymbalta, generic); OR
      - b) Savella (milnacipran tablets); AND
    - iii. Patient has tried, and, according to the prescriber, has experienced inadequate efficacy or significant intolerance with pregabalin capsule or oral solution (Lyrica, generic); OR
  - B) **Patient is continuing therapy with Tonmya.** Approve if according to the prescriber, the patient is having a positive response to Tonmya therapy.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tonmya is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Tonmya™ sublingual tablets [prescribing information]. Chatham, NJ and Audubon, PA: Tonix and Almac; September 2025.
2. Cymbalta® delayed-release capsules [prescribing information]. Indianapolis, IN: Eli Lilly; August 2023.
3. Savella® tablets [prescribing information]. North Chicago, IL: AbbVie; May 2024.
4. Lyrica® capsules and oral solution [prescribing information]. New York, NY: Parke-Davis; June 2020.
5. Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2017;76:318-3289.

### HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/04/2026
Selected Revision	<b>Fibromyalgia:</b> For a patient who is continuing therapy with Tonmya, the criterion that the patient was required to be < 65 years of age was removed.	02/11/2026