



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

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

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.²⁻⁴ The European League Against Rheumatism 2017 guidelines for fibromyalgia treatment recommend a multimodal and individualized approach, emphasizing non-pharmacological interventions as first-line therapy.⁵ 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.

Tonmya™ (cyclobenzaprine hydrochloride sublingual tablets - Tonix Medicines) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

Tonmya™ (cyclobenzaprine hydrochloride sublingual tablets - Tonix Medicines) is(are) considered not medically necessary for ANY other use(s). 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	Fibromyalgia: 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

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