

TonmyaTM (cyclobenzaprine sublingual tablet)

Policy # 00965

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Tonmya^{TM†} (cyclobenzaprine sublingual tablet) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for Tonmya (cyclobenzaprine sublingual tablet) will be considered when the following criteria are met:

- Patient has a diagnosis of fibromyalgia; AND
- Patient is greater than or equal to 18 years of age; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following prescription GENERIC products for the treatment of fibromyalgia for at least TWO months EACH: gabapentin capsules/tablets, pregabalin capsules, duloxetine capsules, OR other generic antidepressants unless there is clinical evidence or patient history that suggests the use of the required products for at least TWO months EACH will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC cyclobenzaprine tablets for at least TWO months unless there is clinical evidence or patient history that suggests the use of the generic cyclobenzaprine tablets for at least TWO months will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Tonmya (cyclobenzaprine sublingual tablet) when the patient has NOT failed treatment with at least TWO of the following prescription generic products for the treatment of fibromyalgia for at least TWO months EACH: gabapentin capsules/tablets, pregabalin capsules, duloxetine capsules, OR other generic antidepressants to be **not medically necessary**.**

Based on review of available data, the Company considers the use of Tonmya (cyclobenzaprine sublingual tablet) when the patient has NOT failed treatment with GENERIC cyclobenzaprine tablets for at least TWO months to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Tonmya (cyclobenzaprine sublingual tablet) for indications other than fibromyalgia to be **investigational**.*

Based on review of available data, the Company considers the use of Tonmya (cyclobenzaprine sublingual tablet) when the patient is less than 18 years of age to be **investigational**.*

Background/Overview

Tonmya is a sublingual formulation of cyclobenzaprine indicated for the treatment of fibromyalgia in adults. Cyclobenzaprine has been available for decades in oral and extended-release formulations for muscle spasm and has been used off-label for fibromyalgia. The mechanism of action of Tonmya in fibromyalgia is unknown; however, cyclobenzaprine is structurally related to tricyclic antidepressants and demonstrates antagonistic activity at serotonergic (5-HT_{2A}), α ₁-adrenergic, H₁-histaminergic, and M₁-muscarinic receptors. Tonmya is administered sublingually once daily at bedtime. Treatment is initiated at 2.8 mg once daily for the first 14 days and increased to a target dose of 5.6 mg once daily thereafter. For geriatric patients and those with mild hepatic impairment, the recommended and maximum dose is 2.8 mg once daily. Use is not recommended in patients with moderate or severe hepatic impairment.

Fibromyalgia

Fibromyalgia is a chronic pain disorder characterized by widespread musculoskeletal pain, fatigue, sleep disturbance, and cognitive symptoms, often accompanied by depression or anxiety. The condition affects approximately 10 million individuals in the United States, predominantly women, and is diagnosed clinically based on symptom patterns and duration rather than laboratory or imaging findings. Treatment goals focus on symptom reduction and improvement in functional status and quality of life. Current management strategies emphasize a multimodal, individualized approach that includes non-pharmacologic therapies as first-line treatment, with pharmacologic options reserved for patients with persistent or severe symptoms.

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Three other medications—pregabalin, duloxetine, and milnacipran (Savella®†)—are FDA-approved for the treatment of fibromyalgia. While these agents and Tonmya have demonstrated modest efficacy in reducing pain and related symptoms, indirect comparisons across trials are limited by differences in study design, patient populations, endpoints, and pharmacologic properties. Fibromyalgia remains a heterogeneous condition with variable treatment response, and pharmacologic options must be weighed against their safety profiles and overall benefit in individual patients.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tonmya (cyclobenzaprine sublingual tablet) was approved in August 2025 for the treatment of fibromyalgia in adults.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Tonmya for the treatment of fibromyalgia was assessed in three randomized, two-arm, parallel-group, double-blind, placebo-controlled multicenter trials: RELIEF, RESILIENT, and RALLY. The trials enrolled 1,474 patients aged 18 to 65 (735 Tonmya-treated patients and 739 placebo-treated patients) who met the 2016 American College of Rheumatology (ACR) criteria for diagnosis of fibromyalgia (including generalized pain, defined as pain in at least 4 of 5 regions; symptoms that had been present at a similar level for at least 3 months; and widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5 , OR WPI between 4 to 6 and SSS scale score ≥ 9).

Patients were randomized to receive bedtime sublingual treatment of either:

- 2.8 mg of Tonmya nightly for the first 2 weeks, and then 5.6 mg of Tonmya beginning on the evening of Day 15 through Week 14.
- Placebo administered through Week 14.

The primary endpoint in all three trials was the change from baseline to Week 14 in the weekly average of daily 24-hour recall pain intensity scores. As measured by the 11-point (0-10) numeric rating scale (NRS), the minimum mean baseline pain score required for enrollment was 4. Within each trial, at baseline, the Tonmya and placebo groups had similar mean weekly averages of daily diary pain scores. Regarding the primary endpoint, in RELIEF the changes from baseline were -1.9 with Tonmya vs. -1.5 with placebo (baseline of 6.1 and 6.0, respectively) [$P = 0.01$]; changes in RESILIENT were -1.8 with Tonmya vs. -1.2 with placebo (baseline of 5.9 in each group) [$P < 0.001$]. Around 46.5% of Tonmya-treated patients had a $\geq 30\%$ reduction in pain intensity by Week 14. Of note, the primary endpoint was not met in RALLY.

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References

1. Tonmya [package insert]. Tonix Pharmaceuticals, Inc. Chatham, New Jersey. Updated August 2025.
2. Tonmya Drug Evaluation. Express Scripts. September 3, 2025.
3. Fibromyalgia: Treatment in adults. UpToDate. Updated September 9, 2025.

Policy History

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

05/07/2026 Medical Policy Committee review

05/13/2026 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 05/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.