Tonmya™
(cyclobenzaprine HCl)
sublingual tablets 2.8mg

Prior Authorization (PA) Checklist

A reference for navigating the PA process

Getting started:

Be sure to review the PA guidelines on the insurer's website or to contact the insurer's customer service for process information, including forms and contacts.

- When requesting information, ask for the Fibromyalgia class, TONMYA, and/or new drug to market policy.
- You may initiate a PA request through BlinkRx, a digital pharmacy service that offers access and support.

WHEN ADDRESSING A PA, MAKE SURE TO INCLUDE:

1 Product and patient information

- [ ] Product name: TONMYA (cyclobenzaprine HCl sublingual tablets)
- [ ] Quantity and dosing
- [ ] Patient full name, gender, address, date of birth
- [ ] Patient pharmacy benefit plan information: plan or PBM name or ID card BIN/PCN/RxGroup

2 Prior treatment documentation

- [ ] Relevant medication name(s) and dosing information
- [ ] Dates and duration of treatment
- [ ] Response to treatment

3 Diagnosis code and clinical information

- [ ] **Potential ICD-10 diagnosis code**

This list is not exhaustive, subject to change without notice, and the code used is the decision of the prescriber. Contact payers for specific information on their coding, coverage, and payment policies.

M79.7: Fibromyalgia[1]

- [ ] Current symptoms and functional status
- [ ] Contraindications
- [ ] Comorbidities
- [ ] Liver status
- [ ] Pregnancy status

Note: Information must be substantiated in the patient medical record and available to payers upon request. Because clear coverage policies may lag new product approvals, it is important to include as much medical information as possible during the PA process.

Abbreviations: ICD-10, International Classification of Diseases, Tenth Revision; PA, prior authorization; PBM, pharmacy benefit manager.

Please see Indication and Important Safety Information on pages 3 and 4 and full Prescribing Information.

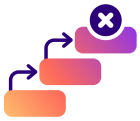
TONIX MEDICINES

Additional Coverage Support

Below are the most frequent reasons payers may reject PA requests.

Missing medical history

↳ Include prior therapy responses, labs, and relevant chart notes



Incomplete step therapy

↳ List drug name, dose, dates, and outcome for each prior medication

Coverage criteria not met

↳ **Review plan's PA form/portal for requirements** (eg, diagnosis, duration, impairment)

Wrong or incomplete form

↳ **Use the correct PA form** (commercial, Medicare, Medicaid) **and complete all fields**

Need PA support for TONMYA?

Remember, you can initiate a PA request through BlinkRx, who can provide PA initiation and information.

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Indication and Important Safety Information

INDICATION

TONMYA is indicated for the treatment of fibromyalgia in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TONMYA is contraindicated:

- In patients with hypersensitivity to cyclobenzaprine or any inactive ingredient in TONMYA. Hypersensitivity reactions may manifest as an anaphylactic reaction, urticaria, facial and/or tongue swelling, or pruritus. Discontinue TONMYA if a hypersensitivity reaction is suspected.
- With concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after discontinuation of an MAO inhibitor. Hyperpyretic crisis seizures and deaths have occurred in patients who received cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitors drugs.
- During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure.
- In patients with hyperthyroidism.

WARNINGS AND PRECAUTIONS

- **Embryofetal toxicity:** Based on animal data, TONMYA may cause neural tube defects when used two weeks prior to conception and during the first trimester of pregnancy. Advise females of reproductive potential of the potential risk and to use effective contraception during treatment and for two weeks after the final dose. Perform a pregnancy test prior to initiation of treatment with TONMYA to exclude use of TONMYA during the first trimester of pregnancy.
- **Serotonin syndrome:** Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome, a potentially life-threatening condition. Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Treatment with TONMYA and any concomitant serotonergic agent should be discontinued immediately if serotonin syndrome symptoms occur and supportive symptomatic treatment should be initiated. If concomitant treatment with TONMYA and other serotonergic drugs is clinically warranted, careful observation is advised, particularly during treatment initiation or dosage increases.
- **Tricyclic antidepressant-like adverse reactions:** Cyclobenzaprine is structurally related to TCAs. TCAs have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke. If clinically significant central nervous system (CNS) symptoms develop, consider discontinuation of TONMYA. Caution should be used when TCAs are given to patients with a history of seizure disorder, because TCAs may lower the seizure threshold. Patients with a history of seizures should be monitored during TCA use to identify recurrence of seizures or an increase in the frequency of seizures.
- **Atropine-like effects:** Use with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic drugs.
- **CNS depression and risk of operating a motor vehicle or hazardous machinery:** TONMYA monotherapy may cause CNS depression. Concomitant use of TONMYA with alcohol, barbiturates, or other CNS depressants may increase the risk of CNS depression. Advise patients not to operate a motor vehicle or dangerous machinery until they are reasonably certain that TONMYA therapy will not adversely affect their ability to engage in such activities.
- **Oral mucosal adverse reactions:** In clinical studies with TONMYA, oral mucosal adverse reactions occurred more frequently in patients treated with TONMYA compared to placebo. Advise patients to moisten the mouth with sips of water before administration of TONMYA to reduce the risk of oral sensory changes (hypoesthesia). Consider discontinuation of TONMYA if severe reactions occur.

Please see additional Important Safety Information on page 4 and full Prescribing Information.

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Important Safety Information (continued)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer.

DRUG INTERACTIONS

- MAO inhibitors: Life-threatening interactions may occur.
- Other serotonergic drugs: Serotonin syndrome has been reported.
- CNS depressants: CNS depressant effects of alcohol, barbiturates, and other CNS depressants may be enhanced.
- Tramadol: Seizure risk may be enhanced.
- Guanethidine or other similar acting drugs: The antihypertensive action of these drugs may be blocked.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Based on animal data, TONMYA may cause fetal harm when administered to a pregnant woman. The limited amount of available observational data on oral cyclobenzaprine use in pregnancy is of insufficient quality to inform a TONMYA-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women about the potential risk to the fetus with maternal exposure to TONMYA and to avoid use of TONMYA two weeks prior to conception and through the first trimester of pregnancy. Report pregnancies to the Tonix Medicines, Inc., adverse-event reporting line at 1–888–869–7633 (1–888–TNXPMED).
- **Lactation:** A small number of published cases report the transfer of cyclobenzaprine into human milk in low amounts, but these data cannot be confirmed. There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TONMYA and any potential adverse effects on the breastfed child from TONMYA or from the underlying maternal condition.
- **Pediatric use:** The safety and effectiveness of TONMYA have not been established.
- **Geriatric patients:** Of the total number of TONMYA-treated patients in the clinical trials in adult patients with fibromyalgia, none were 65 years of age and older. Clinical trials of TONMYA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.
- **Hepatic impairment:** The recommended dosage of TONMYA in patients with mild hepatic impairment (HI) (Child Pugh A) is 2.8 mg once daily at bedtime, lower than the recommended dosage in patients with normal hepatic function. The use of TONMYA is not recommended in patients with moderate HI (Child Pugh B) or severe HI (Child Pugh C). Cyclobenzaprine exposure (AUC) was increased in patients with mild HI and moderate HI compared to subjects with normal hepatic function, which may increase the risk of TONMYA-associated adverse reactions.

Please see additional safety information in the full Prescribing Information.

To report suspected adverse reactions, contact Tonix Medicines, Inc. at 1–888–869–7633, or the FDA at 1–800–FDA-1088 or www.fda.gov/medwatch.

Reference: 1. Centers for Medicare and Medicaid Services. ICD code lists. Accessed July 24, 2025. https://www.cms.gov/medicare/coordination-benefits-recovery/overview/icd-code-lists

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