Tonmya™
(cyclobenzaprine HCl)
sublingual tablets 2.8mg

Quick Start Guide

Helping your patients begin treatment with Tonmya™

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.

Please see additional Important Safety Information on pages 6–7 and full Prescribing Information.

TONIX MEDICINES

Here to help support patient access to TONMYA

Once you have decided that TONMYA is right for your patient, TONMYA can be prescribed and filled in two ways

1 BlinkRx:

Prescribe TONMYA through your EMR to BlinkRx U.S. Boise, Idaho*

BlinkRx is a digital pharmacy service that offers access and support, including:

- Prior authorization (PA) initiation and information
- Financial assistance for eligible patients
- Refill and pharmacy consultative services
- Free nationwide delivery

2 Retail pharmacy:

Prescribe TONMYA to your patient's retail pharmacy of choice

Prior authorization and appeals support

- See our **PA checklist and sample letters** of medical necessity and appeal in this guide

*Valid only for those patients with commercial prescription insurance coverage who meet eligibility criteria. Offer not valid for (i) prescriptions paid, in whole or in part, by any federal, state, or government-funded insurance programs (for example, Medicare, Medicare Advantage, Medigap, Medicaid, Veterans Affairs (VA), Department of Defense (DoD), or TRICARE), (ii) for cash-paying patients, (iii) where product is not covered by patient's commercial insurance, (iv) where patient's commercial insurance plan reimburses them for the entire cost of their prescription drug, or (v) where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any federal, state, or government-funded healthcare program, patient will no longer be able to use the Tonmya Together™ Savings Program and patient must notify Tonix Medicines at 1-844-851-3390 to stop participation. Patients may not seek reimbursement for the value of the out-of-pocket expense covered by the Program from any third-party payer, whether public or private. The Program is valid ONLY for qualifying patients residing in the 50 U.S. states or Puerto Rico with commercial insurance who have a valid prescription for an FDA-approved indication for the qualifying Tonix Medicines therapy. The Program is not health insurance. This offer may not be combined with any other rebate, coupon or offer. Out-of-pocket assistance under the Program is not transferable. Tonix Medicines reserves the right to rescind, revoke, or amend the Program without notice. The patient/caregiver must certify their responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting requirements regarding receipt of Program benefits, if necessary, to any commercial insurer. The Program is subject to termination or modification at any time. Some restrictions apply.

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Tonmya Together™: TONMYA Savings Program

Your eligible, commercially insured patients could pay as little as $0 on their TONMYA prescription

Restrictions apply. Subject to change. See full terms and conditions*

How patients can enroll

Going to TonmyaSavings.com

Texting 'TONMYA' to 833-700-4766†

If you or your patients have questions about the Savings Card, please call 1 (844) 851-3390 from Monday through Friday between 9 AM ET and 5:30 PM ET.

*Valid only for those patients with commercial prescription insurance coverage who meet eligibility criteria. Offer not valid for (i) prescriptions paid, in whole or in part, by any federal, state, or government-funded insurance programs (for example, Medicare, Medicare Advantage, Medigap, Medicaid, Veterans Affairs (VA), Department of Defense (DoD), or TRICARE), (ii) for cash-paying patients, (iii) where product is not covered by patient's commercial insurance, (iv) where patient's commercial insurance plan reimburses them for the entire cost of their prescription drug, or (v) where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any federal, state, or government-funded healthcare program, patient will no longer be able to use the Tonmya Together™ Savings Program and patient must notify Tonix Medicines at 1-844-851-3390 to stop participation. Patients may not seek reimbursement for the value of the out-of-pocket expense covered by the Program from any third-party payer, whether public or private. The Program is valid ONLY for qualifying patients residing in the 50 U.S. states or Puerto Rico with commercial insurance who have a valid prescription for an FDA-approved indication for the qualifying Tonix Medicines therapy. The Program is not health insurance. This offer may not be combined with any other rebate, coupon or offer. Out-of-pocket assistance under the Program is not transferable. Tonix Medicines reserves the right to rescind, revoke, or amend the Program without notice. The patient/caregiver must certify their responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting requirements regarding receipt of Program benefits, if necessary, to any commercial insurer. The Program is subject to termination or modification at any time. Some restrictions apply.

†Message and data rates may apply. Message frequency varies. Please see TonmyaSavings.com for Eligibility Criteria and full Terms and Conditions. Once enrolled, text HELP for help. Text STOP to end.

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Prior authorization (PA) checklist

This checklist is designed to support your practice in navigating a PA for TONMYA. Use it to help streamline the PA process and minimize delays

Be sure to obtain the proper PA form for the patient's specific health plan.
You may also initiate a PA request through BlinkRx.

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.

This information is also available in a standalone resource that can be accessed at www.TonmyaHCP.com

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

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Optional coverage support

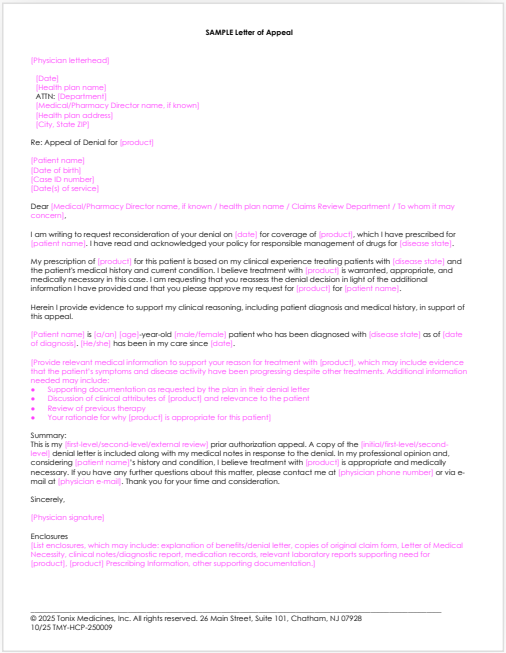
If coverage is not initially approved, you and your patient have the option to submit an appeal to the health plan

- Determine the reason for the denial (eg, missing information, trial and failure of a first-line product, etc) and submit the required information/documentation
- The payer is required to respond to each level of appeal within a specified period and offer both standard and expedited processes[2]
- Be sure to check each health plan's specific time frame and appeal options
- For commercial payers, appeal instructions are typically included in the denial letter

Letters of appeal and medical necessity may be required

- Letters of medical necessity **justify the clinical rationale** for prescribing a specific drug by explaining why it is medically necessary for the patient
- Letters of appeal formally **challenge the health plan's denial** of the PA request

Sample letter of appeal



SAMPLE Letter of Appeal

[Physician letterhead]

[Date]
[Health plan name]
ATTN: [Department]
[Medical/Pharmacy Director name, if known]
[Health plan address]
[City, State ZIP]

Re: Appeal of Denial for [product]

[Patient name]
[Date of birth]
[Case ID number]
[Date(s) of service]

Dear [Medical/Pharmacy Director name, if known / health plan name / Claims Review Department / To whom it may concern],

I am writing to request reconsideration of your denial on [date] for coverage of [product], which I have prescribed for [patient name]. I have read and acknowledged your policy for responsible management of drugs for [disease state].

My prescription of [product] for this patient is based on my clinical experience treating patients with [disease state] and the patient's medical history and current condition. I believe treatment with [product] is warranted, appropriate, and medically necessary in this case. I am requesting that you reassess the denial decision in light of the additional information I have provided and that you please approve my request for [product] for [patient name].

Herein I provide evidence to support my clinical reasoning, including patient diagnosis and medical history, in support of this appeal.

[Patient name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [disease state] as of [date of diagnosis]. [He/she] has been in my care since [date].

[Provide relevant medical information to support your reason for treatment with [product], which may include evidence that the patient's symptoms and disease activity have been progressing despite other treatments. Additional information needed may include:
- Supporting documentation as requested by the plan in their denial letter
- Discussion of clinical attributes of [product] and relevance to the patient
- Review of previous therapy
- Your rationale for why [product] is appropriate for this patient]

Summary:
This is my [first-level/second-level/external review] prior authorization appeal. A copy of the [initial/first-level/second-level] denial letter is included along with my medical notes in response to the denial. In my professional opinion and, considering [patient name]'s history and condition, I believe treatment with [product] is appropriate and medically necessary. If you have any further questions about this matter, please contact me at [physician phone number] or via e-mail at [physician e-mail]. Thank you for your time and consideration.

Sincerely,

[Physician signature]

Enclosures
[List enclosures, which may include: explanation of benefits/denial letter, copies of original claim form, Letter of Medical Necessity, clinical notes/diagnostic report, medication records, relevant laboratory reports supporting need for [product], [product] Prescribing Information, other supporting documentation.]

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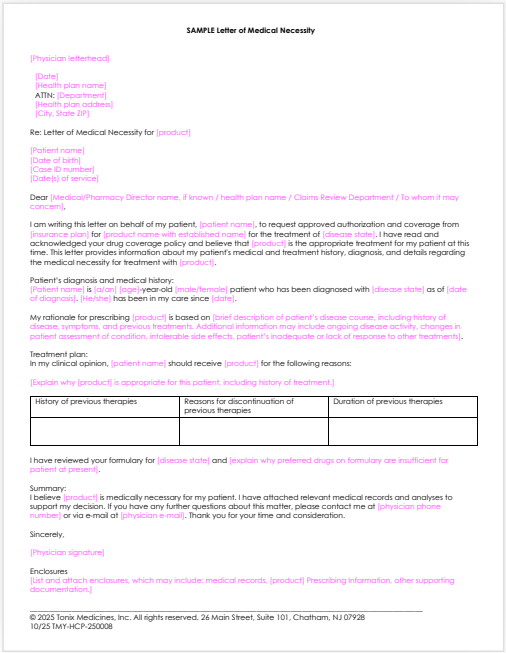
Sample letter of medical necessity



SAMPLE Letter of Medical Necessity

[Physician letterhead]

[Date]
[Health plan name]
ATTN: [Department]
[Health plan address]
[City, State ZIP]

Re: Letter of Medical Necessity for [product]

[Patient name]
[Date of birth]
[Case ID number]
[Date(s) of service]

Dear [Medical/Pharmacy Director name, if known / health plan name / Claims Review Department / To whom it may concern],

I am writing this letter on behalf of my patient, [patient name], to request approved authorization and coverage from [insurance plan] for [product name with established name] for the treatment of [disease state]. I have read and acknowledged your drug coverage policy and believe that [product] is the appropriate treatment for my patient at this time. This letter provides information about my patient's medical and treatment history, diagnosis, and details regarding the medical necessity for treatment with [product].

Patient's diagnosis and medical history:
[Patient name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [disease state] as of [date of diagnosis]. [He/she] has been in my care since [date].

My rationale for prescribing [product] is based on [brief description of patient's disease course, including history of disease, symptoms, and previous treatments. Additional information may include ongoing disease activity, changes in patient assessment of condition, intolerable side effects, patient's inadequate or lack of response to other treatments].

Treatment plan:
In my clinical opinion, [patient name] should receive [product] for the following reasons:

[Explain why [product] is appropriate for this patient, including history of treatment.]

History of previous therapies	Reasons for discontinuation of previous therapies	Duration of previous therapies

I have reviewed your formulary for [disease state] and [explain why preferred drugs on formulary are insufficient for patient at present].

Summary:
I believe [product] is medically necessary for my patient. I have attached relevant medical records and analyses to support my decision. If you have any further questions about this matter, please contact me at [physician phone number] or via e-mail at [physician e-mail]. Thank you for your time and consideration.

Sincerely,

[Physician signature]

Enclosures
[List and attach enclosures, which may include: medical records, [product] Prescribing Information, other supporting documentation.]

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Sample letters of appeal and medical necessity may be downloaded here: www.TonmyaHCP.com

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Indication and Important Safety Information

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- 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 7 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.

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References

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

2. Patient Advocate Foundation. A patient's guide to navigating the insurance appeals process. Accessed March 5, 2025. https://www.patientadvocate.org/wp-content/uploads/Navigating-the-insurance-appeals-guide-pages.pdf

Questions?
Contact BlinkRx for support resources

BLINKRx

Support resources

Provider may call in or fax the prescription directly to BlinkRx.

Phone: 1 (844) 926-2480
Fax: 1 (866) 585-4631

BlinkRx hours:

Monday-Friday 8am-9pm EST,
Saturdays 9am-5pm EST

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