UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2387-1
Program	Prior Authorization/Medical Necessity
Medication	Tonmya™ (cyclobenzaprine sublingual tablet)
P&T Approval Date	12/2025
Effective Date	3/1/2026

1. Background:

Tonmya (cyclobenzaprine sublingual tablet) is indicated for treatment of fibromyalgia in adults.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Tonmya** will be approved based on **all** of the following criteria:

   a. Diagnosis of fibromyalgia

   -AND-

   b. Fibromyalgia diagnosed based on **all** of the following American College of Rheumatology criteria:

      1) Generalized pain, defined as pain in at least 4 of 5 regions, is present
      2) Symptoms have been present at a similar level for at least 3 months
      3) Diagnosis of fibromyalgia is valid irrespective of other diagnoses.
      4) Diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses
      5) And **one** of the following:

         a) Widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5

         -OR-

         b) WPI of 4–6 and SSS score ≥ 9

   -AND-

   c. Patient has implemented **all** of the following nonpharmacologic measures for the treatment of fibromyalgia

      1) Patient education (e.g., sleep hygiene)
      2) Physical activity and exercise
      3) Cognitive therapy (e.g. meditation and relaxation, cognitive-behavioral therapy, mindfulness-based stress reduction)

-AND-

d. Submission of medical records (e.g. chart notes) documenting a failure or intolerance to cyclobenzaprine (generic Flexeril) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

-AND-

e. History of failure, contraindication, or intolerance to **two** of the following:

1) amitriptyline (generic Elavil)
2) duloxetine (generic Cymbalta)
3) gabapentin (generic Neurontin)
4) pregabalin (generic Lyrica)
5) Savella

Authorization will be issued for 12 months.

B. Reauthorization

1. **Tonmya** will be approved based on the following criteria:

a. Documentation of a reduction in pain intensity with Tonmya use

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Tonmya [package insert]. Chatham, NJ: Tonix Medicines, Inc; ;
2. Clauw, D. J. (2025). *Fibromyalgia: Treatment in adults*. In J. E. Ware & D. M. Drossman (Eds.), UpToDate. Wolters Kluwer. Retrieved November 6, 2025, from https://www.uptodate.com
3. Wolfe, F., Clauw, D. J., Fitzcharles, M.-A., et. al (2016). 2016 revisions to the 2010/2011 fibromyalgia diagnostic criteria. *Seminars in Arthritis and Rheumatism*, *46*(3), 319–329.

Program	Prior Authorization/Medical Necessity Tonmya
Change Control	
12/2025	New program.