

# Initial Step Therapy; Post Step Therapy Prior Authorization

## Tonmya

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tonmya	cyclobenzaprine

### Indications

#### FDA-approved Indications

Tonmya is indicated for treatment of fibromyalgia in adults.

### Initial Step Therapy

If the patient has filled a prescription for at least a 30 day supply of immediate-release pregabalin or duloxetine within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

# Coverage Criteria

## Fibromyalgia

Authorization may be granted when the requested drug is being prescribed for the treatment of fibromyalgia when ALL of the following criteria are met:

- The patient is 18 years of age or older.
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to duloxetine OR pregabalin.
  - The patient has experienced an intolerance to duloxetine OR pregabalin.
  - The patient has a contraindication that would prohibit a trial of ALL of the following: duloxetine, pregabalin.

## Continuation of Therapy

## Fibromyalgia

Authorization may be granted when the requested drug is being prescribed for the treatment of fibromyalgia when ALL of the following criteria are met:

- The patient is 18 years of age or older.
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in pain).

## Duration of Approval (DOA)

- 7143-D: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months.

## References

1. Tonmya [package insert]. Chatham, NJ: Tonix Pharmaceuticals, Inc.; August 2025.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed August 27, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/27/2025).
4. Winslow BT; Vandal C; Dang, L. Fibromyalgia: Diagnosis and Management. American Family Physician. February 2023; 107(2): 137-144.