

STEP THERAPY POLICY

- POLICY:** Antiepileptics – Topiramate Step Therapy Policy
- Qudexy® XR (topiramate extended-release capsules – Upsher-Smith, generics, including an authorized generic)
 - Topamax® (topiramate tablets and sprinkle capsules – Ortho-McNeil Neurologics, generics)
 - Trokendi XR® (topiramate extended-release capsules – Supernus)

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OVERVIEW

Topiramate and topiramate extended-release (XR) are indicated for the following:^{1,3}

- Initial monotherapy for the treatment of **partial onset or primary generalized tonic-clonic seizures** in patients ≥ 2 years of age.
- Adjunctive therapy for the treatment of **partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut Syndrome** in patients ≥ 2 years of age.
- Preventive treatment of **migraine headache** in patients ≥ 12 years of age.

Trokendi XR is indicated for the following:²

- Initial monotherapy for the treatment of **partial onset or primary generalized tonic-clonic seizures** in patients ≥ 6 years of age.
- Adjunctive therapy for the treatment of **partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome** in patients ≥ 6 years of age.
- Prophylaxis of **migraine headache** in patients ≥ 12 years of age.

Topiramate tablets and sprinkle capsules are dosed twice daily for all indications.¹ Trokendi XR and topiramate XR are dosed once daily.^{2,3}

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic topiramate tablets, generic topiramate sprinkle capsules

Step 2: Qudexy XR (brand and generics), Topamax tablets, Topamax Sprinkle Capsules, Trokendi XR, Topiramate ER capsules (branded product)

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Topamax[®] tablets, sprinkle capsules [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; June 2020.
2. Trokendi XR[®] extended-release capsules [prescribing information]. Rockville, MD: Supernus Pharmaceuticals, Inc.; February 2019.
3. Qudexy[®] XR extended-release capsules [prescribing information]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; February 2020.