Cigna National Formulary Coverage Policy

Effective Date.. 4/17/2023
Next Review Date...................................... 4/17/2024

Step Therapy
Antiseizure Medications – Topiramate

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Product Identifier(s)

Effective 1/1/23 to 4/11/23: 109563

Effective 4/12/23: 52014

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected
- Eprontia™ (topiramate oral solution)
- Qudexy® XR (topiramate extended-release capsules – generics, including an authorized generic)
- Topamax® (topiramate tablets and sprinkle capsules, generic)
- Trokendi XR® (topiramate extended-release capsules)

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.

Step 1: generic topiramate tablets, generic topiramate sprinkle capsules

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

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Topiramate and topiramate extended-release (XR) are indicated for the following uses:[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 (brand and generic) is indicated for the following uses:[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.

Eprontia is indicated for the following uses:[4]

- 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.

Topiramate sprinkle capsules may be swallowed whole or may be administered by sprinkling the entire contents of a capsule on a small amount (teaspoon) of soft food.[1]

References

1. Topamax® tablets, sprinkle capsules [prescribing information]. Titusville, NJ: Janssen; October 2022.
2. Trokendi XR® extended-release capsules [prescribing information]. Rockville, MD: Supernus; October 2022.
3. Qudexy® XR extended-release capsules [prescribing information]. Maple Grove, MN: Upsher-Smith; December 2022.
4. Eprontia™ oral solution [prescribing information]. Wilmington, MA: Azurity; October 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	12/07/2022
Selected Revision	**Policy Name Change:** Changed from Antiepileptics – Topiramate to Antiseizure Medications – Topiramate. **Generic to Trokendi XR:** This agent was added to the policy as a Step 2 product.	02/01/2023

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