STEP THERAPY POLICY

POLICY: Antiseizure Medications – Topiramate Step Therapy Policy
- Eprontia® (topiramate oral solution – Azurity)
- Qudexy® XR (topiramate extended-release capsules – Upsher-Smith, generic, including an authorized generic)
- Topamax® (topiramate tablets and sprinkle capsules – Ortho-McNeil, generic)
- Topiramate sprinkle capsule (brand product)
- Trokendi XR® (topiramate extended-release capsules – Supernus, generic)

REVIEW DATE: 12/04/2024; selected revision 03/05/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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]

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.

Step 1: generic topiramate tablets, generic topiramate sprinkle capsules

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

Antiseizure Medications – Topiramate Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

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

REFERENCES

1. Topamax® tablets, sprinkle capsules [prescribing information]. Titusville, NJ: Janssen; May 2023.
2. Trokendi XR® extended-release capsules [prescribing information]. Rockville, MD: Supernus; January 2024.
3. Qudexy® XR extended-release capsules [prescribing information]. Maple Grove, MN: Upsher-Smith; March 2024.

4. Eprontia® oral solution [prescribing information]. Woburn, MA: Azurity; May 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/06/2023
Annual Revision	No criteria changes.	12/04/2024
Selected Revision	**Topiramate Sprinkle Capsule (branded product):** Added to the policy as a Step 2 Product.	03/05/2025