Clinical Policy: Topiramate Extended-Release (Qudexy XR, Trokendi XR)

Reference Number: CP.PMN.281
Effective Date: 09.01.22
Last Review Date: 08.22
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Topiramate extended-release (Qudexy® XR, Trokendi XR®) is a sulfamate-substituted monosaccharide.

FDA approved indication

Qudexy XR is indicated:

- As initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older.
- As 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 and older.
- For the preventive treatment of migraine in patients 12 years of age and older.

Trokendi XR is indicated:

- As initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older.
- As 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 and older.
- For the preventive treatment of migraine in patients 12 years of age and older.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Qudexy XR and Trokendi XR are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Partial-onset Seizures, Primary Generalized Tonic-Clonic Seizures, or Lennox-Gastaut Syndrome (must meet all)**:**

1. Diagnosis of partial-onset seizures, primary generalized tonic-clonic seizures or Lennox-Gastaut syndrome;
2. Age ≥ 2 years old for Qudexy XR, ≥ 6 years old for Trokendi XR;

3. Failure of a trial of generic immediate-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
4. For Qudexy XR and Trokendi XR, failure of generic extended-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed:
   a. Monotherapy for adults and pediatric patients ≥ 10 years old: 400 mg/day;
   b. Monotherapy for patients 2 years to < 10 years of age:

Weight (kg)	Maximum Daily Dose
Up to 11	250 mg
12 to 22	300 mg
23 to 31	350 mg
32 to 38	350 mg
Greater than 38	400 mg

   c. Adjunctive therapy for patients ≥ 17 years of age: 400 mg/day;
   d. Adjunctive therapy for patients ≤ 16 years of age: 9 mg/kg/day up to 400 mg/day.

Approval duration:
HIM/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Migraine Prophylaxis (must meet all)**:**
1. Diagnosis of migraine headaches that require prophylaxis;
2. Age ≥ 12 years old;
3. Failure of a trial of generic immediate-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
4. For Qudexy XR and Trokendi XR, failure of generic extended-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed: 100 mg/day.

Approval duration:
HIM/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Partial Seizures, Primary Generalized Seizures, Tonic-Clonic Seizures, or Lennox-Gastaut Syndrome (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Qudexy XR or Trokendi XR for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Monotherapy for adults and pediatric patients ≥10 years old: 400 mg/day;
   b. Monotherapy for patients 2 years to < 10 years of age:

Weight (kg)	Maximum Daily Dose
Up to 11	250 mg
12 to 22	300 mg
23 to 31	350 mg
32 to 38	350 mg
Greater than 38	400 mg

   c. Adjunctive therapy for patients ≥ 17 years of age: 400 mg/day;
   d. Adjunctive therapy for patients ≤ 16 years of age: 9 mg/kg/day up to 400 mg/day.

Approval duration:
HIM/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Migraine Prophylaxis (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Failure of a trial of generic immediate-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
4. For Qudexy XR and Trokendi XR, failure of generic extended-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed 100 mg daily.

Approval duration:
HIM/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –

CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Topiramate, immediate-release (Topamax®)	150 to 400 mg per day based on age and indication	150 to 400 mg/day based on age and indication

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Qudexy XR: none reported
  - Trokendi XR: with recent alcohol use (i.e., within 6 hours prior to and 6 hours after Trokendi XR use)
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Topiramate extended release (Qudexy XR)	Seizures	Adults: 200 to 400 mg PO QD Pediatric patients 2 years to < 10 years of age monotherapy: 150 mg to 400 mg PO QD Pediatric patients ≥ 2 years old adjunctive therapy: 5 mg/kg to 9 mg/kg PO QD	Adults and monotherapy for pediatric patients ≥ 2 years old: 400 mg/day Pediatric patients ≥ 2 years old as adjunctive therapy: 9 mg/kg/day up to 400 mg/day
	Migraine Prophylaxis	25 to 100 mg PO QD	100 mg/day
Topiramate extended release (Trokendi XR)	Seizures	Adults: 200 to 400 mg PO QD	Adults and monotherapy for

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Pediatric patients 6 years to < 10 years of age monotherapy: 150 mg to 400 mg PO QD Pediatric patients 6 to <10 years of age adjunctive therapy: 5 mg/kg to 9 mg/kg PO QD	pediatric patients ≥ 6 years: 400 mg/day Adjunctive therapy for pediatric patients ≥ 6 years old: 9 mg/kg/day up to 400 mg/day
	Migraine Prophylaxis	25 to 100 mg PO QD	100 mg/day

VI. Product Availability

Drug	Availability
Topiramate extended release (Qudexy XR)	Capsule: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg
Topiramate extended release (Trokendi XR)	Capsule: 25 mg, 50 mg, 100 mg, 200 mg

VII. References

1. Trokendi XR Prescribing Information Winchester, KY: Catalent Pharma Solutions; February 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/201635s029lbl.pdf. Accessed May 25, 2022.
2. Qudexy XR Prescribing Information Maple Grove, MN; Upsher-Smith Laboratories, LLC; February 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205122s012lbl.pdf. Accessed May 25, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per May SDC and prior clinical guidance.	05.20.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.