

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

Reference Number: CP.PMN.281

Effective Date: 09.01.22

Last Review Date: 08.24

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<sup>®</sup> XR, Trokendi XR<sup>®</sup>) 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<sup>®</sup> 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 is one of the following (a or b):
  - a. Qudexy XR:  $\geq 2$  years;
  - b. Trokendi XR:  $\geq 6$  years;

3. Member meets one of the following (a or b):
  - a. Request is for the treatment of a member in a State with limitations on step therapy in certain settings (*see Appendix D*);
  - b. Both of the following (i and ii):
    - i. Member must use generic immediate-release topiramate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
    - ii. For Qudexy XR and Trokendi XR, member must use generic extended-release topiramate (generic Qudexy) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed:
  - a. Monotherapy for adults and pediatric members  $\geq 10$  years of age: 400 mg per day;
  - b. Monotherapy for members 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 members  $\geq 17$  years of age: 400 mg per day;
- d. Adjunctive therapy for members  $\leq 16$  years of age: 9 mg/kg per day up to 400 mg per 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  $\geq 12$  years;
3. Member must use 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, member must use generic extended-release topiramate (generic Qudexy) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 100 mg per day.

**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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

- CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
- b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Partial-Onset 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 members ≥ 10 years of age: 400 mg per day;
  - b. Monotherapy for members 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 members ≥ 17 years of age: 400 mg per day;
- d. Adjunctive therapy for members ≤ 16 years of age: 9 mg/kg per day up to 400 mg per day.

**Approval duration:**

**HIM/Medicaid** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

**B. Migraine Prophylaxis (must meet all):**

- 1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- 2. Member is responding positively to therapy;
- 3. Member must use 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, member must use generic extended-release topiramate (generic Qudexy) 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 per day.

**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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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.*

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
topiramate, immediate-release (generic for Topamax <sup>®</sup> )	150 to 400 mg per day based on age and indication	150 to 400 mg/day based on age and indication

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
topiramate, extended-release (generic for Qudexy XR)	<p><b>Seizures</b> <u>Monotherapy</u> Adults and pediatric patients <math>\geq 10</math> years of age: 400 mg PO QD</p> <p>Pediatric patients 2 – 9 years of age: 150 mg to 400 mg PO QD</p> <p><u>Adjunctive therapy</u> Adults (<math>\geq 17</math> years old): 200 mg to 400 mg PO QD</p> <p>Pediatric patients 2 – 16 years old: 5 mg/kg to 9 mg/kg PO QD</p> <p><b>Migraine Prophylaxis</b> 100 mg PO QD</p>	<p><b>Seizures</b> 150 to 400 mg/day based on age and indication</p> <p><b>Migraine Prophylaxis</b> 100 mg/day</p>

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

*Appendix C: Contraindications/Boxed Warnings*

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

*Appendix D: States with Limitations against Redirections in Certain Settings*

State	Step Therapy Prohibited?	Notes
NV	No	<p><i>*Applies to Medicaid requests only*</i></p> <p>Failure of ONE of the following, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated: generic immediate-release topiramate or generic extended-release topiramate (generic Qudexy).</p>

**V. Dosage and Administration**

Drug Name	Indication	Dosing Regimen	Maximum Dose
Topiramate extended release (Qudexy XR)	Seizures	<p><u>Monotherapy</u> Adults and pediatric patients <math>\geq 10</math> years of age: 400 mg PO QD</p>	Adults and monotherapy for pediatric patients $\geq 2$ years old: 400 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Pediatric patients 2 – 9 years of age: 150 mg to 400 mg PO QD  <u>Adjunctive therapy</u> Adults (≥ 17 years old): 200 mg to 400 mg PO QD  Pediatric patients 2 – 16 years old: 5 mg/kg to 9 mg/kg PO QD	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	<u>Monotherapy</u> Adults and pediatric patients ≥ 10 years of age: 400 mg PO QD  Pediatric patients 6 years to < 10 years of age monotherapy: 150 mg to 400 mg PO QD  <u>Adjunctive therapy</u> Adults (≥ 17 years old): 200 mg to 400 mg PO QD  Pediatric patients 6 to 16 years of age adjunctive therapy: 5 mg/kg to 9 mg/kg PO QD	Adults and monotherapy for pediatric patients ≥ 6 years: 400 mg/day  Adjunctive therapy for pediatric patients 6 – 16 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)	Capsules: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg
Topiramate extended release (Trokendi XR)	Capsules: 25 mg, 50 mg, 100 mg, 200 mg

#### VII. References

1. Trokendi XR Prescribing Information Winchester, KY: Catalent Pharma Solutions; January 2024. Available at: <https://www.trokendixrhcp.com/>. Accessed May 14, 2024.

2. Qudexy XR Prescribing Information Maple Grove, MN; Upsher-Smith Laboratories, LLC; March 2024. Available at: <https://www.qudexyxr.com>. Accessed June 5, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per May SDC and prior clinical guidance.	05.20.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
Clarified redirection language from “failure of” to “member must use” for generic extended-release topiramate redirection.	01.04.23	
Added clarification for generic extended-release formulation redirection as “generic Qudexy.”	02.03.23	
3Q 2023 annual review: no significant changes; references reviewed and updated.	05.18.23	08.23
For partial-onset seizures, primary generalized tonic-clonic seizures, and Lennox-Gastaut syndrome, added redirection bypass for members in a State with limitations on step therapy in certain settings along with Appendix D, which includes Nevada with requirements for single drug redirection for Medicaid requests.	08.31.23	
3Q 2024 annual review: no significant changes; revised “Failure of a trial” language to template “Member must use” language; references reviewed and updated.	05.14.24	08.24

**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.

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**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.

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