



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/20/14
LAST REVIEW DATE: 11/16/17
LAST CRITERIA REVISION DATE: 11/16/17
ARCHIVE DATE:

QUDEXY™ XR (topiramate) extended-release capsule TROKENDI™ XR (topiramate) extended-release capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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QUDEXY™ XR (topiramate) extended-release capsule
TROKENDI™ XR (topiramate) extended-release capsule (cont.)

Description:

Qudexy XR (topiramate) extended-release capsules are indicated as initial monotherapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures; as adjunctive therapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures (safety and effectiveness in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials); as adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome; and for prophylaxis of migraine in individuals 12 years of age and older. The usefulness of Qudexy XR (topiramate) in the acute treatment of migraine headache has not been established.

Trokendi XR (topiramate) extended-release capsules are indicated as initial monotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures (safety and effectiveness in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials); as adjunctive therapy in patients 6 years of age and older with partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome; and for prophylaxis of migraine in individuals 12 years of age and older. The usefulness of Trokendi XR (topiramate) in the acute treatment of migraine headache has not been established.

BCBSAZ covers Topiramate Capsule ER with applicable quantity level limits without precertification. Qudexy™ XR and Trokendi XR™ require precertification and approval is based on medical necessity and failure of Topiramate Capsule ER.

Qudexy XR (topiramate)
Trokendi XR (topiramate)

Medication class:

Anticonvulsant, miscellaneous

FDA-approved indication(s):

- Qudexy XR
 - Initial monotherapy in patients 2 years and older with partial-onset or primary generalized tonic-clonic seizures
 - Adjunctive therapy in patients 2 years and older with partial-onset seizures, or primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome
 - Prophylaxis of migraine headache in patients 12 years and older
- Trokendi XR
 - Initial monotherapy in patients 6 years and older with partial-onset or primary generalized tonic-clonic seizures
 - Adjunctive therapy in patients 6 years and older with partial-onset seizures, or primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome
 - Prophylaxis of migraine headache in patients 12 years and older

**QUDEXY™ XR (topiramate) extended-release capsule
TROKENDI™ XR (topiramate) extended-release capsule (cont.)**

Recommended Doses:

- Qudexy XR and Trokendi XR:
 - Epilepsy Monotherapy 10 years of age or older:
 - Recommended dose is 400 mg once daily
 - Initiate 50 mg once daily, increase by 50 mg at weekly intervals x 4 weeks then 100 mg for weeks 5 to 6
 - Epilepsy Monotherapy 2 years of age to < 10 years of age:
 - Target minimum and maximum doses are based on patient kilogram weight
 - Initial dose should be 25 mg once daily x 1 week, then 50 mg once daily in the 2nd week
 - Increase by 25-50 mg once daily at weekly intervals to the minimum dose over 5-7 weeks
 - Adjunctive therapy 17 years of age or older:
 - Total daily dose 200-400 mg once daily
 - Initiate at 25-50 mg once daily, increase by 25-50 mg every week, dose above 1,600 mg have not been studied
 - Adjunctive therapy 2 years of age to 16 years of age:
 - Total daily dose 5-9 mg/kg once daily
 - Initiate 1-3 mg/kg/day for the first week, increase at 1-2 week intervals by 1-3 mg/kg
 - Migraine 12 years of age and older:
 - Recommended dose is 100 mg once daily
 - 25 mg once daily x 1 week, increase by 25 mg at weekly interval

Maximum dosage

- No maximum stated but high doses may predispose to development of metabolic acidosis

Available Dosage Forms:

- Qudexy XR: 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg capsules
- Trokendi XR: 25 mg, 50 mg, 100 mg, and 200 mg capsules

Warnings and Precautions:

- Usefulness in the acute treatment of migraine headache has not been studied
- Safety and effectiveness in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials
- Adjust dose for renal impairment (creatinine clearance < 70 mL/min/1.73 m²)
- A supplemental dose may be needed during hemodialysis
- Serum bicarbonate level should be measured before initiation and periodically is recommended
- Acute or chronic metabolic acidosis may occur, chronic metabolic acidosis may increase risk for nephrolithiasis or nephroncalcinosis, osteomalacia, osteoporosis, and increase risk for fracture
 - Manifestations include hyperventilation, fatigue, anorexia, hypercloremia, and decreased serum bicarbonate
- Use with caution with other drugs that cause metabolic acidosis or with a ketogenic diet
- If metabolic acidosis develops and persists, consider reducing dose or dose tapering to discontinue
- Hyperammonemia with or without encephalopathy can occur, also dose related and may occur with or without simultaneous use of valproic acid
 - Clinical symptoms of hyperammonemic encephalopathy often includes acute change in level of consciousness and/or cognitive function with lethargy or vomiting
- Hypothermia may occur when used with valproic acid

**QUDEXY™ XR (topiramate) extended-release capsule
TROKENDI™ XR (topiramate) extended-release capsule (cont.)**

- Hyperthermia and oligohydrosis (decreased sweating) can occur, especially in pediatric patients
- Acute myopia and secondary angle closure glaucoma and other visual field defects occur that are reversible on discontinuation
- Topiramate is a carbonic anhydrase inhibitor, can promote stone formation by reducing urinary citrate excretion and by increasing urinary pH
- Avoid simultaneous use with other carbonic anhydrase inhibitors [acetazolamide, dichlorphenamide (Daramide, Keveyis), zonisamide]
- Woman of child bearing potential should use effective contraception
- Qudexy XR and Trokendi XR once daily provide similar steady state topiramate levels to immediate release topiramate taken every 12 hours, when given at the same total daily dose
- Qudexy XR capsules can be opened and sprinkled on food, Trokendi XR capsules cannot be opened

Criteria:

- **Criteria for initial therapy:** Qudexy XR (topiramate) or Trokendi XR (topiramate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:
1. Individual is **ONE** of the following:
 - For Qudexy XR:
 - Individual is 2 years of age or older with **EITHER** of the following:
 - a confirmed diagnosis of partial onset seizure **or** primary generalized tonic-clonic seizure to be used as initial monotherapy or adjunctive therapy
 - a confirmed diagnosis of seizures associated with Lennox-Gastaut syndrome to be used as adjunctive therapy
 - Individual is 12 years of age and older with the following:
 - a confirmed diagnosis of migraine to be used prophylactic therapy
 - For Trokendi XR:
 - Individual is 6 years of age or older with **EITHER** of the following:
 - a confirmed diagnosis of partial onset seizure **or** primary generalized tonic-clonic seizures to be used as initial monotherapy or as adjunctive therapy
 - a confirmed diagnosis of seizures associated with Lennox-Gastaut syndrome to be used as adjunctive therapy
 - Individual is 12 years of age and older with the following:
 - a confirmed diagnosis of migraine to be used prophylactic therapy
 2. Individual has failure, contraindication, or intolerance to Topiramate Capsule ER
 3. **ALL** of the following baseline tests have been completed before initiation of treatment:
 - Serum bicarbonate
 4. There are **NO** contraindications:
 - Contraindications include:

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TROKENDI™ XR (topiramate) extended-release capsule (cont.)**

- For Quedexy XR and Trokendi XR:
 - Metabolic acidosis when used simultaneously with Metformin
- For Trokendi XR:
 - Recent alcohol use (6 hours before and after)

Initial approval duration: 12 months

➤ **Criteria for continuation of coverage (renewal request):** Quedexy XR (topiramate) or Trokendi XR (topiramate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
 - Response is defined as:
 - For seizure disorder there has been a reduction in the number of seizures over baseline
 - For migraine prophylaxis there has been a reduction in the frequency of migraine headaches
2. Individual has been adherent with the medication
3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section
4. There are no significant interacting drugs

Renewal duration: 12 months

Resources:

Qudexy™ XR. Package Insert. Reference ID 3469214. Revised by manufacturer 3-11-2014 Accessed 11-6-2014.

Trokendi XR™. Package Insert. Reference ID 3357981. Revised by manufacturer 8-18-2013. Accessed 11-6-2014. Reviewed 10-12-2015.

Qudexy™ XR. Package Insert. Revised by manufacturer 3/2015. Reviewed 10-12-2015.

Qudexy™ XR. Package Insert. Revised by manufacturer 5/2016. Reviewed 09-27-2016.

Trokendi XR™. Package Insert. Revised by manufacturer 8/2016. Reviewed 09-27-2016.



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UpToDate: Preventive treatment of migraine in adults. Current through Sep 2017. https://www.uptodate-com.mwu.idm.oclc.org/contents/preventive-treatment-of-migraine-in-adults?source=search_result&search=migraine%20prophylaxis&selectedTitle=1~73

UpToDate: Preventive treatment of migraine in children. Current through Sep 2017. https://www.uptodate-com.mwu.idm.oclc.org/contents/preventive-treatment-of-migraine-in-children?source=search_result&search=migraine%20prophylaxis&selectedTitle=2~73#H534631570



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
 Call 866-325-1794 to check the status of a request.
 All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
 Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> No There is absence of ALL contraindications.	

4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.
 Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.

For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:

Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.