



Topiramate ER Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

POLICY REVIEW CYCLE

Effective Date
06-01-2024

Date of Origin
01-01-2019

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Qudexy XR® (topiramate ER)* Capsules	Epilepsy: initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut Syndrome in patients 2 years of age or older Preventative treatment of migraine in patients 12 years of age and older	*generic available	1
Trokendi XR® (topiramate ER)* Capsules	Epilepsy: initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox Gastaut syndrome in patients 6 years of age and older Preventative treatment of migraine in patients 12 years of age and older	*generic available	2

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Safety	Qudexy XR has no FDA labeled contraindications for use.(1) Trokendi XR is contraindicated in patients with recent alcohol use (i.e., within 6 hours prior to and 6 hours after Trokendi XR use).(2)
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REFERENCES

Number	Reference
1	Qudexy XR prescribing information. Upsher-Smith Laboratories, LLC. December 2022.
2	Trokendi XR prescribing information. Supernus Pharmaceuticals Inc. October 2022.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Trokendi xr	topiramate cap er	100 MG ; 200 MG ; 25 MG ; 50 MG	M ; N ; O ; Y	O ; Y		
Qudexy xr	topiramate cap er	100 MG ; 150 MG ; 200 MG ; 25 MG ; 50 MG	M ; N ; O ; Y	O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 100 MG	100 MG	30	Capsules	30	DAYS			
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 150 MG	150 MG	30	Capsules	30	DAYS			
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 200 MG	200 MG	60	Capsules	30	DAYS			
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 25 MG	25 MG	30	Capsules	30	DAYS			
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 50 MG	50 MG	30	Capsules	30	DAYS			
Trokendi xr	Topiramate Cap ER 24HR 100 MG	100 MG	30	Capsules	30	DAYS			
Trokendi xr	Topiramate Cap ER 24HR 200 MG	200 MG	60	Capsules	30	DAYS			
Trokendi xr	Topiramate Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS			
Trokendi xr	Topiramate Cap ER 24HR 50 MG	50 MG	30	Capsules	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qudexy xr	topiramate cap er	100 MG ; 150 MG ; 200 MG ; 25 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trokendi xr	topiramate cap er	100 MG ; 200 MG ; 25 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 100 MG	100 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 150 MG	150 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 200 MG	200 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 25 MG	25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Qudexy xr	Topiramate Cap ER 24HR Sprinkle 50 MG	50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trokendi xr	Topiramate Cap ER 24HR 100 MG	100 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trokendi xr	Topiramate Cap ER 24HR 200 MG	200 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trokendi xr	Topiramate Cap ER 24HR 25 MG	25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trokendi xr	Topiramate Cap ER 24HR 50 MG	50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has been treated with an anti-seizure medication that is not topiramate OR B. The patient has ONE of the following diagnoses: <ol style="list-style-type: none"> 1. Partial onset seizures OR

Module	Clinical Criteria for Approval
	<p>2. Primary generalized tonic-clonic seizures OR</p> <p>3. Lennox-Gastaut Syndrome OR</p> <p>4. Migraine AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <p>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND</p> <p>2. ONE of the following:</p> <p>A. The patient has a medication history of use of an anti-seizure medication that is not topiramate OR</p> <p>B. The patient has had clinical benefit with the requested agent AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <p>1. The requested quantity (dose) does NOT exceed the program quantity limit OR</p> <p>2. ALL of the following:</p> <p>A. The requested quantity (dose) exceeds the program quantity limit AND</p> <p>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND</p> <p>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit OR</p> <p>3. ALL of the following:</p> <p>A. The requested quantity (dose) exceeds the program quantity limit AND</p> <p>B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND</p> <p>C. There is support for therapy with a higher dose for the requested indication</p> <p>Length of Approval: up to 12 months</p>