



Extended Release Topiramate Products

Policy # 00534

Original Effective Date: 01/01/2017

Current Effective Date: 08/14/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider extended release topiramate products, including but not limited to Qudexy[®] XR, Trokendi[®] XR, generic topiramate ER sprinkle capsules, and generic topiramate ER capsules to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for extended release topiramate products, including but not limited to Qudexy XR, Trokendi XR, generic topiramate ER sprinkle capsules, or generic topiramate ER capsules when the following criteria are met:

- Patient meets ONE of the following:
 - Patient has a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome; OR
 - Patient will utilize the requested drug for the prevention of migraine headaches AND the patient is 12 years of age or older; AND
- Patient must meet the following:
 - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO other GENERIC prescription products for the chosen condition (one of which MUST be topiramate immediate release) UNLESS there is clinical evidence or patient history that suggests the use of TWO other generic prescription products for the chosen condition will be/was ineffective or will/did cause an adverse reaction to the patient; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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- If the request is for brand Trokendi XR, patient has tried and failed (e.g., intolerance or inadequate response) generic topiramate ER capsules **UNLESS** there is clinical evidence or patient history that suggests the use of generic topiramate ER capsules will be/was ineffective or will/did cause an adverse reaction to the patient.
(*Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met*).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of extended release topiramate products, including but not limited to Qudexy XR, Trokendi XR, generic topiramate ER sprinkle capsules, and generic topiramate ER capsules **WITHOUT** having tried and failed (e.g., intolerance or inadequate response) at least **TWO** other generic prescription products for the chosen condition (one of which **MUST** be topiramate immediate release) to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of extended release topiramate products, including but not limited to Qudexy XR, Trokendi XR, generic topiramate ER sprinkle capsules, and generic topiramate ER capsules for any indication other than their respective FDA approved indications to be **investigational.***

Background/Overview

Qudexy XR is indicated for initial monotherapy as well as adjunctive therapy in those with partial onset seizures or primary generalized tonic-clonic seizures. It is also indicated for adjunctive therapy in patients with seizures that are associated with Lennox-Gastaut Syndrome. Qudexy XR is available in 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg extended release capsules. Qudexy XR has a generic equivalent, topiramate ER sprinkle capsules, and anywhere that Qudexy XR is mentioned in this section, the same information applies to the generic equivalent. Trokendi XR carries similar indications as Qudexy XR with a slight variation in age ranges. Trokendi XR is available in 25 mg, 50 mg, 100 mg, and 200 mg extended release capsules with a generic equivalent available for each

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strength. Topiramate is available in an immediate release formulation, which is generic. All of the branded extended release topiramate products are also approved for the prevention of migraine headaches in patients 12 years of age or older. The generic immediate release formulation carries the same indications as the extended release products.

The Trokendi XR package insert notes that Trokendi XR's basis for approval was the demonstration of pharmacokinetic equivalence of Trokendi XR to immediate release topiramate. Qudexy XR's package insert notes that its approval was of a similar bioequivalence nature, but it did have a placebo-controlled trial in which it did show statistical significance. There are various generic options for these epileptic conditions, including but not limited to carbamazepine, divalproex sodium, lamotrigine, levetiracetam, phenytoin, etc. Various alternatives (most of which are generic) are available for the prevention of migraine headaches, including beta blockers (e.g. propranolol, nadolol, metoprolol, timolol), antidepressants (e.g. amitriptyline, venlafaxine), antiepileptics (e.g. valproate), calcium channel blockers (verapamil), or botulinum toxins (brand only). If approval was previously given for a botulinum toxin product for the prevention of migraine headaches, then use of the botulinum toxin will suffice for use of the second generic product. It does NOT override use of topiramate immediate release. Given the clinical information regarding the extended release topiramate products and the availability of generic alternatives, the use of the alternative generic products is a clinically and economically sensible option.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Trokendi XR was approved in 2013 while Qudexy was approved in 2014. Both carry similar indications (mentioned in the background/overview section), however age approvals vary slightly.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests at least TWO other generic prescription products for the chosen condition (one of which MUST be topiramate immediate release) will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using extended release topiramate products, including but not limited to Qudexy XR, Trokendi XR, and generic topiramate ER sprinkle capsules over at least TWO other generic prescription products for the chosen condition (one of which MUST be topiramate immediate release). If approval was previously given for a botulinum toxin product for the prevention of migraine headaches, then use of the botulinum toxin will suffice for use of the second generic product. It does NOT override use of topiramate immediate release. This policy is also in place to ensure that the drugs are being used for their FDA approved indications.

References

1. Qudexy XR [package insert]. Upsher-Smith Laboratories, Inc. Maple Grove, Minnesota. Updated March 2017.
2. Trokendi XR [package insert]. Supernus Pharmaceuticals, Inc. Rockville, Maryland. Updated March 2017.

Policy History

Original Effective Date: 01/01/2017

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10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. New policy.
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Added new indication of prevention of migraine headaches for those 12 years of age or older.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. No change to coverage.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. No change to coverage.
01/07/2021	Medical Policy Committee review

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- 01/13/2021 Medical Policy Implementation Committee approval. Corrected formatting of the patient selection criteria to clarify true intent.
- 01/06/2022 Medical Policy Committee review
- 01/12/2022 Medical Policy Implementation Committee approval. Switched the branded generic of Qudexy XR to the generic equivalent topiramate ER sprinkle capsules to reflect its change from single source brand to generic.
- 01/05/2023 Medical Policy Committee review
- 01/11/2023 Medical Policy Implementation Committee approval. No change to coverage.
- 07/06/2023 Medical Policy Committee review
- 07/12/2023 Medical Policy Implementation Committee approval. Added generic topiramate ER capsules to policy.

Next Scheduled Review Date: 07/2024

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

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would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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