

Commercial/Healthcare Exchange PA Criteria

Effective: June 2014

Prior Authorization: Qudexy XR, Trokendi XR

Products Affected: Qudexy XR (topiramate) extended-release capsule, Trokendi XR (topiramate) extended-release capsule, topiramate ER capsules

Medication Description:

The exact mechanism of action is unknown, but 4 properties that may contribute to topiramate's antiepileptic and antimigraine efficacy are a blockage of voltage-dependent sodium channels, an augmentation of gamma-aminobutyrate acid activity at some subtypes of the GABA- A receptors, antagonism of AMPA/kainate subtype of the glutamate receptor, and inhibition of the carbonic anhydrase enzyme, particularly isozymes II and IV.

Covered Uses:

1. Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older.
2. 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
3. Prophylaxis of migraine headache in patients 12 years of age and older

Exclusion Criteria:

1. Recent alcohol use (i.e., within 6 hours prior to and 6 hours after Trokendi XR use)

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed
3. Medical history

Age Restrictions:

Partial-onset or primary generalized tonic-clonic seizures: 2 years of age and older
Prophylaxis of migraine headache: 12 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

Partial-onset or primary generalized tonic-clonic seizures

- A. Patient has diagnosis of partial-onset or primary generalized tonic-clonic seizures;
- B. Patient has had an intolerance to or treatment failure with generic immediate release topiramate.

Migraine Prophylaxis

- A. Patient has clinically diagnosed chronic migraine as defined by:
 - a. Patient has been diagnosed as having at least four or more migraines a month; AND

- B. Patient has prior usage, in the last 18 months, of at least TWO standard prophylactic pharmacologic therapies, each from a different pharmacologic class, used to prevent migraines or reduce migraine frequency including:
 - a. Beta-blockers (i.e. propranolol, metoprolol, atenolol);
 - b. Calcium Channel blockers (i.e. verapamil);
 - c. Anti-epileptics (i.e. as topiramate IR or divalproex sodium);
 - d. Antidepressants (venlafaxine OR a tricyclic antidepressant such as amitriptyline or nortriptyline); AND
- C. Patient has had an intolerance to or treatment failure with generic immediate release topiramate.

References:

1. Trokendi XR full prescribing information. Rockville, MD, Supernus Pharmaceuticals
2. Qudexy XR full prescribing information. Maple Grove, MN, Upsher-Smith Pharmaceuticals
3. Neurology 2012;78;1337-1345. S.D. Silberstein, S. Holland, F. Freitag, et al.
4. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	06/2014
2	Update	New CCI Template Revision History: 9/15, 2/16, 11/16, 2/17 Added FDA approved indication of migraine prophylaxis for Qudexy XR Addition of age restrictions per indications (new starts) Clinical criteria added to define chronic migraine	All	02/03/2020

3	Update	Topiramate ER capsules added to products affected Specified topiramate dosage form as IR	Products affected Other criteria	2/18/2021
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