

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	Qudexy XR (topiramate) extended-release capsules (sprinkles) Trokendi XR (topiramate) extended-release capsule
POLICY #	11119
INDICATIONS	<p><u>QUDEXY XR is an antiepileptic drug indicated for:</u></p> <p><u>Partial Onset Seizures and Primary Generalized Tonic-Clonic Seizures -</u></p> <ul style="list-style-type: none">Initial monotherapy in patients with partial onset or primary generalized tonic-clonic seizures, and adjunctive therapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures <p><u>Lennox-Gastaut Syndrome (LGS)</u></p> <ul style="list-style-type: none">Adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome <p><u>TROKENDI XR is an antiepileptic drug indicated for:</u></p> <p><u>Partial Onset Seizures and Primary Generalized Tonic-Clonic Seizures -</u></p> <ul style="list-style-type: none">Initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy 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 <p><u>Lennox-Gastaut Syndrome (LGS)</u></p> <ul style="list-style-type: none">Adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome <p>Non-FDA Labeled indications:</p> <p><u>Migraine Prophylaxis</u></p> <ul style="list-style-type: none">Trokendi XR and Qudexy XR are considered appropriate treatment for prophylaxis of migraine headache in adults and adolescents 12 years and older who have failed a trial of immediate release topiramate.
CRITERIA	ConnectiCare considers Qudexy XR and Trokendi XR to be medically necessary for patients who meet the following criteria: <ul style="list-style-type: none">Patient is diagnosed with seizure disorder OR <ul style="list-style-type: none">Patient is 12 years or older and has been clinically diagnosed with migraine headaches (not FDA-Approved)

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	AND <ul style="list-style-type: none">• Patient has a documented intolerance to, or treatment failure of an adequate trial of Topamax (topiramate) tablets AND <ul style="list-style-type: none">• Patient has had an intolerance to, or treatment failure of, 2 other preventative medications (including, but not limited to tricyclic antidepressants, beta blockers or other anticonvulsants).
REFERENCES	<ol style="list-style-type: none">1. Trokendi XR full prescribing information. Rockville, MD, Supernus Pharmaceuticals2. Qudexy XR full prescribing information. Maple Grove, MN, Upsher-Smith Pharmaceuticals3. 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
P&T REVIEW HISTORY	6/14, 10/14, 11/15, 2/16, 2/17, 1/18
REVISION RECORD	9/15, 2/16, 11/16, 2/17