Anticonvulsants, Non-Preferred

Aptiom® (eslicarbazepine); Banzel® (rufinamide); Fycompa™ (perampanel);
Keppra XR® (levetiracetam extended-release); Lamictal™ (lamotrigine extended-
release, lamotrigine orally dissolving tablets); Onfi (clobazam); Oxtellar XR™
(oxcarbazepine extended-release tablets); Peganone (Ethotoin); Potiga™
(ezogabine); Quedexy™ XR (topiramate extended-release); Trokendi XR®
(topiramate extended-release); Vimpat (lacosamide)

Effective: 1/1/15

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If the request is for Lyrica or Sabril, please see individual drug-specific medical necessity guidelines.

OVERVIEW

Lennox-Gastaut syndrome (LGS) is a rare and severe form of epilepsy that is characterized by a triad of mixed seizure patterns, impaired intellectual development, and electroencephalography (EEG) abnormalities. It has been shown to occur in 5% of patients with epilepsy. Males are more likely to be affected than females. The onset is often seen between one year of age to eight years of age; and peaks at three years of age to five years of age. Due to the complexity of the disorder, an accurate diagnosis is often difficult. Diagnosis is based on clinical features and EEG readings. Patients with LGS must present with three main criteria: different seizure types, mental retardation or learning disabilities, and a specific EEG pattern of slow spike and wave discharges at < 2.5 Hz. Most pediatric neurologists consider valproic acid the first-line treatment for LGS but only topiramate, lamotrigine, clobazam, rufinamide, and felbamate are FDA-approved for use in this disorder.

FDA-APPROVED INDICATIONS

Aptiom (eslicarbazepine) is indicated as adjunctive therapy in the treatment of partial-onset seizures. Safety and efficacy has not been established in children.

Banzel (rufinamide) is indicated as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults.

Fycompa (perampanel) is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy who are 12 years and older.

Keppra XR (levetiracetam) is indicated for adjunctive therapy in the treatment of partial onset seizures in patients 12 years of age and older with epilepsy.

Lamictal (lamotrigine immediate-release) is indicated as adjunctive therapy for partial seizures, the generalized seizures of Lennox-Gastaut syndrome, and primary generalized tonic-clonic seizures in adults and children 2 years and older. The immediate-release formulation only is also indicated for the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes (depression, mania, hypomania, mixed episodes) in adults treated for acute mood episodes with standard therapy.

Lamictal XR (lamotrigine extended-release) is indicated for primary generalized tonic-clonic seizures and partial-onset seizures with or without secondary generalization in patients 13 years and older.

Oxtellar XR (oxcarbazepine) is indicated for adjunctive therapy in the treatment of partial onset seizures in patients 6 years of age and older.
Onfi (clobazam) is a benzodiazepine indicated as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.

Peganone (ethotoin) is indicated for the control of tonic-clonic and complex partial (psychomotor) seizures.

Potiga (ezogabine) is indicated for adjunctive treatment for partial-onset seizures in patients 18 years and older.

Quedexy XR/Trokendi XR (topiramate extended-release) is indicated for initial monotherapy in patients 10 years of age and older 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. It is also indicated as adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome.

Vimpat® (lacosamide) is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 17 years and older with epilepsy.

**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of non-preferred anticonvulsant agents for members when all the following criteria for a particular regimen are met and limitations do not apply:

**Aptiom, Fycompa, Potiga, Vimpat**
- Documented diagnosis of partial-onset seizures by a neurologist
- One of the following:
  - The member is stable on the medication
  - The member has had an insufficient response or intolerance to at least two other medications indicated for adjunct partial seizures*

*Examples of alternative medications indicated for adjunct partial seizures:
  - Felbatol® (felbamate)
  - Gabitril® (tiagabine)
  - Lamictal® (lamotrigine)
  - Lyrica® (pregabalin)
  - Keppra® / Keppra XR™ (levetiracetam)
  - Neurontin® (gabapentin)
  - Tegretol (carbamazepine)
  - Topamax® (topiramate)
  - Trileptal® (oxcarbazepine)
  - Zonegran® (zonisamide)

**Banzel**
- The member is diagnosed with Lennox-Gastaut syndrome (LGS) or an epileptic condition associated with LGS made by a neurologist
- One of the following:
  - The member is currently stable on Banzel
  - The member tried and failed therapy with, or has a contraindication or an intolerance to at least two of the following alternative anticonvulsant agents: valproic acid derivative (Depakene, Depakote), topiramate (Topamax), lamotrigine (Lamictal), felbamate (Felbatol), clobazam (Onfi)

**Felbamate (Felbatol)**
- The member is diagnosed with epilepsy or a condition associated with a seizure disorder
- Therapy with two alternative anticonvulsant agents has been insufficient

**Keppra XR**
- The member is diagnosed with epilepsy or a condition associated with a seizure disorder
- Therapy with immediate-release levetiracetam has been insufficient

**Lamotrigine (Lamictal XR, Lamictal ODT)**
For lamotrigine extended-release (Lamictal XR),
- The member is diagnosed with epilepsy or a condition associated with a seizure disorder
- Therapy with immediate-release lamotrigine has been insufficient

For lamotrigine orally dissolving tablets (Lamictal ODT),
- The member is diagnosed with epilepsy or a condition associated with a seizure disorder
- The member tried and failed therapy with, is intolerant to, or is unable to take oral lamotrigine tablets
• For doses that exceed 75mg per day, the member tried and failed therapy with, is intolerant to, or is unable to take the chewable lamotrigine tablets

Onfi
• The member is diagnosed with Lennox-Gastaut syndrome (LGS) or an epileptic condition associated with LGS made by a neurologist
• One of the following:
  o The member is currently stable on Banzel
  o The member tried and failed therapy with, or has a contraindication or an intolerance to at least two of the following alternative anticonvulsant agents: valproic acid derivative (Depakene, Depakote), topiramate (Topamax), lamotrigine (Lamictal), felbamate (Felbatol), rufinamide (Banzel)

Oxtellar XR
• The member is diagnosed with epilepsy or a condition associated with a seizure disorder
• Therapy with immediate-release oxcarbazepine has been insufficient

Peganone
• The member is diagnosed with epilepsy or a condition associated with a seizure disorder
• Therapy with phenytoin has been insufficient

Trokendi XR
• The member is diagnosed with epilepsy or a seizure disorder and is at least 6 years of age
• One of the following:
  o The member is new to our health plan and is already stable on the medication
  o Therapy with immediate-release topiramate has been insufficient

Upon renewal,
• The member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is medically necessary.

LIMITATIONS
Approval duration is limited to one year.
If renewal criteria are unmet, only a 2-month supply will be approved.
Quantity limits apply as follows:
  Keppra XR: six tablets per day (500 mg); four tablets per day (750 mg)
  Lamictal XR: three tablets per day
  Onfi: two tablets per day
  Oxtellar XR: one tablet per day (150 mg and 300 mg), and four tablets per day (600 mg)
  Quedexy XR: one capsule per day (25 mg, 50 mg, 100 mg); two capsules per day (150 mg, 200 mg)
  Trokendi XR: one capsule per day (25 mg, 50 mg, 100 mg); two capsules per day (200 mg)
  Vimpat: two tablets (or 40 ml) per day

CODES
None

REFERENCES
4. Lamictal XR (lamotrigine) [prescribing information]. Research Triangle Park, NC; June 2014.
5. Onfi (clobazam) [prescribing information]. Deerfield, IL: Lundbeck; November 2013.
8. Trokendi XR (topiramate extended-release) [prescribing information]. Winchester, Kentucky: Catalent Pharma Solutions; August 2013.
15. LaRoche SM, Helmers SL. The new antiepileptic drugs: scientific review. JAMA. 2004a; 291(5); 605-14.
16. LaRoche SM, Helmers SL. The new antiepileptic drugs: clinical applications. JAMA. 2004b; 291(5); 614-620.

APPROVAL HISTORY
• June 12, 2014: Non-Preferred Anticonvulsant guideline (Aptiom, Fycompa, Potiga, Vimpat) was reviewed by the Pharmacy and Therapeutics Committee
• November 4, 2014: Reviewed by the Pharmacy and Therapeutics Committee. Changes include: approval durations changed to 1 year; renewal criteria added; individual criteria consolidated to a single document.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.