Clinical Policy: Lacosamide (Vimpat)

Reference Number: IL.ERX.PMN.155
Effective Date: 06.01.21
Last Review Date: 08.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lacosamide (Vimpat®) is an anticonvulsant.

FDA Approved Indication(s)

Vimpat is indicated for the treatment of:

- Partial-onset seizures in patients 4 years of age and older.
- Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Vimpat is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Partial-Onset Seizures (must meet all)**:**

1. Diagnosis of partial-onset seizures and primary generalized tonic-clonic seizures;
2. Age ≥ 4 years;
3. Failure of 2 preferred anticonvulsants, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed (a or b):
   a. Age ≥ 17 years: 400 mg per day;
   b. Age 4 to < 17 years (i, ii, or iii):
      i. Weight ≥ 50 kg: 400 mg per day;
      ii. Weight 30 kg to < 50 kg: 8 mg/kg per day;
      iii. Weight 11 kg to < 30 kg: 12 mg/kg per day.

Approval duration: 12 months

B. Primary Generalized Tonic-Clonic Seizures (must meet all)**:**

1. Diagnosis of primary generalized tonic-clonic seizures;
2. Age ≥ 4 years;
3. Failure of two preferred alternatives (*see Appendix B for examples*) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Vimpat will be used as adjunctive therapy;
5. Dose does not exceed any of the following (a or b):
   a. Age ≥ 17 years: 400 mg per day;
   b. Age 4 to < 17 years (i, ii, or iii):
      i. Weight ≥ 50 kg: 400 mg per day;
      ii. Weight 30 kg to < 50 kg: 8 mg/kg per day;
      iii. Weight 11 kg to < 30 kg: 12 mg/kg per day.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving Vimpat for seizures and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Age ≥ 17 years: 400 mg per day;
   b. Age 4 to < 17 years (i, ii, or iii):
      i. Weight ≥ 50 kg: 400 mg per day;
      ii. Weight 30 kg to < 50 kg: 8 mg/kg per day;
      iii. Weight 11 kg to < 30 kg: 12 mg/kg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Class	Examples	Dose Limit/ Maximum Dose
Anticonvulsants for partial seizures	carbamazepine (Tegretol®), felbamate (Felbatol®), gabapentin (Neurontin®), lamotrigine (Lamictal®), levetiracetam (Keppra®), oxcarbazepine (Trileptal®), phenytoin (Dilantin®), tiagabine (Gabitril®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®), zonisamide (Zonegran®)	Varies according to the agent used
Anticonvulsants for tonic-clonic seizures	carbamazepine (Tegretol®), lamotrigine (Lamictal®), levetiracetam (Keppra®), phenytoin (Dilantin®), primidone (Mysoline®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®)	Varies according to the agent used

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial-onset seizures, primary generalized tonic-clonic seizures	*Adults (17 years and older):* Initial dosage for monotherapy is 100 mg BID; Initial dosage for adjunctive therapy is 50 mg BID. *Pediatric Patients 4 Years to less than 17 years*: The recommended dosage is based on body weight and is administered PO BID.	*Adults (17 years and older):* 400 mg per day *Pediatric Patients 4 Years to less than 17 years*: ≥ 50 kg: 400 mg/day 30 kg to < 50 kg: 8 mg/kg/day 11 kg to < 30 kg: 12 mg/kg/day

VI. Product Availability

- Tablets: 50 mg, 100 mg, 150 mg, 200 mg
- Oral solution: 10 mg/mL
- Single-dose vial for intravenous use: 200 mg/20 mL

VII. References

1. Vimpat Prescribing Information. Smyrna, GA: UCB, Inc.; November 2020. Available at: www.vimpat.com. Accessed July 17, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 17, 2021.
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018; 91 (2)
4. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018; 91 (2)

views, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21
3Q 2021 annual review: added criteria for FDA-approved indication for generalized tonic-clonic seizures; references reviewed updated.	07.16.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.