Clinical Policy: Lacosamide (Vimpat)

Reference Number: PA.CP.PMN.155
Effective Date: 4.17.19
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Revision Log

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.

As the safety of Vimpat injection in pediatric patients has not been established, Vimpat injection is indicated for the treatment of partial-onset seizures only in adult patients (17 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.

It is the policy of health plans affiliated with PA Health & Wellness® 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;
2. Age ≥ 4 years;
3. Failure of 2 preferred alternatives (*see Appendix B for examples*) unless all are contraindicated or clinically significant adverse effects are experienced or member was started and stabilized on Vimpat;
4. Dose does not exceed (a or b):
   a. Age ≥ 17 years or weight ≥ 50 kg: 400 mg/day;
   b. Age 4 to < 17 years (i or ii):
      i. Weight 30 kg to < 50 kg: 8 mg/kg/day;
      ii. Weight 11 kg to < 30 kg: 12 mg/kg/day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 or weight ≥ 50 kg: 400 mg/day;
   b. Age 4 to < 17 years (i or ii):
      i. Weight 30 kg to < 50 kg: 8 mg/kg/day;
      ii. Weight 11 kg to < 30 kg: 12 mg/kg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

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 – PA.CP.PMN.53 for Medicaid 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

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

Not applicable

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial-onset seizures	*Adults (17 years and older):* Initial dosage for monotherapy is 100 mg twice daily; initial dosage for adjunctive therapy is 50 mg twice daily. *Pediatric Patients 4 Years to less than 17 years*: The recommended dosage is based on body weight and is administered orally twice daily.	*Adults (17 years and older):* 400 mg per day *Pediatric Patients 4 Years to less than 17 years*: ≥ 50 kg: 400 mg per 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 2017. Available at: www.vimpat.com. Accessed March 28, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy Created	4/17/19	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	