Clinical Policy: Lacosamide (Vimpat)

Reference Number: CP.PMN.155
Effective Date: 12.01.14
Last Review Date: 08.19
Line of Business: HIM, 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.

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 Centene Corporation® 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;
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): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Vimpat for partial-onset 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 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 Centene benefit and documentation supports positive response to therapy.
   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): HIM.PHAR.21 for health insurance marketplace and 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 policies – HIM.PHAR.21 for health insurance marketplace and 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 / Boxed Warnings

- Contraindication(s): None reported
- Boxed warning(s): None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial-onset 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 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 2018. Available at: www.vimpat.com. Accessed May 19, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 19, 2019.
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)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format.	08.16	08.16
Converted to new template Added max dose. Updated references.	04.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Dosing updated per FDA expanded indication for pediatric patients. Age requirement added per safety guidance endorsed by Centene Medical Affairs.	11.15.17	
3Q 2018 annual review: new policy for Medicaid line of business; modified number of preferred trials from 3 to 2; references reviewed and updated.	04.04.18	08.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	05.05.19	08.19

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.