Clinical Policy: Lacosamide (Motpoly XR, Vimpat)

Reference Number: CP.PMN.155
Effective Date: 12.01.14
Last Review Date: 08.23
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

Lacosamide (Motpoly XR, Vimpat®) is an anticonvulsant.

FDA Approved Indication(s)

Motpoly XR is indicated for the treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg.

Vimpat is indicated:

- For the treatment of partial-onset seizures in patients 1 month of age and older.
- As 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.

It is the policy of health plans affiliated with Centene Corporation® that Motpoly XR and Vimpat are **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. For Vimpat: Age ≥ 1 month;
3. For Motpoly XR: Weight ≥ 50 kg;
4. Member meets one of the following (a or b):
   a. Request is for the treatment of a member in a State with limitations on step therapy in certain settings (*see Appendix D*);
   b. All the following (i, ii, and iii)
      i. Failure of two preferred alternatives (*see Appendix B for examples*), unless clinically significant adverse effects are experienced or all are contraindicated;
      ii. If request is for brand Vimpat, member must use generic lacosamide, unless contraindicated or clinically significant adverse effects are experienced;
      iii. If request is for Motpoly XR, member must use generic immediate-release lacosamide (generic Vimpat), at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. If request is for intravenous (IV) Vimpat, oral Vimpat administration is temporarily not feasible (e.g., status epilepticus, reliance on gastrostomy tube, recent oral or neck surgery, esophageal condition or intraoral infection, myasthenia gravis or other neuromuscular condition);
6. Dose does not exceed any of the following (a or b):
    a. Age ≥ 17 years (i and ii):
        i. 400 mg per day;
        ii. One of the following (1 or 2):
            1) 2 tablets or capsules per day;
            2) 40 mL per day;
    b. Age 1 month to < 17 years (i, ii, iii, or iv):
        i. Weight ≥ 50 kg: 400 mg per day;
        ii. Weight 30 kg to < 50 kg: 8 mg/kg per day;
        iii. Weight 6 kg to < 30 kg: 12 mg/kg per day;
        iv. Weight < 6 kg: 15 mg/kg per day.

Approval duration: 12 months (oral formulation); 1 month (IV formulation)

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

1. Diagnosis of primary generalized tonic-clonic seizures;
2. Request is for Vimpat;
3. Age ≥ 4 years;
4. Member meets one of the following (a or b):
    a. Request is for the treatment of a member in a State with limitations on step therapy in certain settings (*see Appendix D*);
    b. Both of the following (i and ii)
        i. Failure of two preferred alternatives (*see Appendix B for examples*), unless clinically significant adverse effects are experienced or all are contraindicated;
        ii. If request is for brand Vimpat, member must use generic lacosamide, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for intravenous (IV) Vimpat, oral Vimpat administration is temporarily not feasible (e.g., status epilepticus, reliance on gastrostomy tube, recent oral or neck surgery, esophageal condition or intraoral infection, myasthenia gravis or other neuromuscular condition);
6. Vimpat will be used as adjunctive therapy;
7. Dose does not exceed any of the following (a or b):
    a. Age ≥ 17 years (i and ii):
        i. 400 mg per day;
        ii. One of the following (1 or 2):
            1) 2 tablets per day;
            2) 40 mL 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 (oral formulation); 1 month (IV formulation)

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Motpoly XR or 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 brand Vimpat, member must use generic lacosamide, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for intravenous (IV) Vimpat, oral Vimpat administration is temporarily not feasible (e.g., status epilepticus, reliance on gastrostomy tube, recent oral or neck surgery, esophageal condition or intraoral infection, myasthenia gravis or other neuromuscular condition);
5. If request is for a dose increase, new dose does not exceed any of the following (a or b):
   a. Age ≥ 17 years (i and ii):
      i. 400 mg per day;
      ii. One of the following (1 or 2):
         1) 2 tablets or capsules per day;
         2) 40 mL per day;
   b. Age 1 month to < 17 years (i, ii, iii, or iv):
      i. Weight ≥ 50 kg: 400 mg per day;
      ii. Weight 30 kg to < 50 kg: 8 mg/kg per day;
      iii. Weight 6 kg to < 30 kg: 12 mg/kg per day;
      iv. Weight < 6 kg: 15 mg/kg per day.

Approval duration: 12 months (oral formulation); 1 month (IV formulation)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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 – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

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

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
lacosamide, immediate-release (generic for Vimpat®)	45 to 400 mg per day based on age and indication	45 to 400 mg/day based on age and indication
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

Appendix D: States with Limitations against Redirections in Certain Settings

State	Step Therapy Prohibited?	Notes
NV	No	**Applies to Medicaid requests only** Failure of ONE of the following, unless all are contraindicated or clinically significant adverse effects are experienced: generic lacosamide or preferred alternative (*see Appendix B for examples*).

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Immediate-release lacosamide (Vimpat)	Partial-onset seizures, primary generalized tonic-clonic seizures	*Adults (17 years and older):* Initial dosage for monotherapy is 100 mg PO or IV BID; Initial dosage for adjunctive therapy is 50 mg PO or IV BID. *Pediatric patients 1 month old to < 17 years old*: The recommended dosage is based on body weight and is administered PO BID or IV TID.	*Adults (17 years and older):* 400 mg/day *Pediatric patients 4 Years to less than 17 years*: ≥ 50 kg: 400 mg/day 30 kg to < 50 kg: 8 mg/kg/day 6 kg to < 30 kg: 12 mg/kg/day < 6 kg: 15 mg/kg/day
Extended-release lacosamide (Motpoly XR)	Partial-onset seizures	*Adults (17 years and older):* Initial dosage for monotherapy is 200 mg PO or IV QD; Initial dosage for adjunctive therapy is 100 mg PO or IV QD. *Pediatric patients weighing ≥ 50 kg*: Initial dosage is 100 mg PO or IV QD.	*Adults (17 years and older):* 400 mg/day *Pediatric patients weighing ≥ 50 kg*: 400 mg/day

VI. Product Availability

Drug Name	Availability
Immediate-release lacosamide (Vimpat)	• Tablets: 50 mg, 100 mg, 150 mg, 200 mg • Oral solution: 10 mg/mL (200 mL) • Single-dose vial for intravenous use: 200 mg/20 mL
Extended-release lacosamide (Motpoly XR)	Capsules: 100 mg, 150 mg, 200 mg

VII. References

1. Vimpat Prescribing Information. Smyrna, GA: UCB, Inc.; April 2023. Available at: https://www.vimpat.com. Accessed May 18, 2023.
2. Motpoly XR Prescribing Information. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; May 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216185s000lbl.pdf. Accessed May 18, 2023.
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. Neurology. July 10, 2018; 91(2):74-81.
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. Epilepsy Curr. Jul-Aug 2018;18(4):269-78.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9254	Injection, lacosamide, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.05.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: added criteria for FDA-approved indication for generalized tonic-clonic seizures; added HCPCS code; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	04.20.21	08.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: policy updated to reflect newly FDA-approved pediatric age extension down to 1 month of age for partial-onset seizures.	12.09.21	
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22
Per August SDC, added generic redirection for brand requests; HIM line of business removed. Template changes applied to other diagnoses/indications.	08.23.22	11.22
3Q 2023 annual review: consistent with the previously P&T-approved approach for other IV anticonvulsant agents, added a requirement for documentation that the oral formulation is temporarily not feasible; specified that the existing 12 month approval duration applies to only the oral formulation and revised to allow only 1 month for the IV formulation; for continuation criteria for brand Vimpat added a requirement for prior trial of generic lacosamide; references reviewed and updated. RT4: added Motpoly XR to the policy as a newly FDA-approved dose formulation.	05.18.23	08.23
Added redirection bypass for members in a State with limitations on step therapy in certain settings along with Appendix D, which includes Nevada with requirements for single drug redirection for Medicaid requests.	08.31.23	

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.