Clinical Guideline



Oscar Clinical Guideline: Lacosamide (Vimpat) (PG056, Ver. 6)

Lacosamide (Vimpat)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Lacosamide (Vimpat) is an anticonvulsant indicated for the treatment of partial seizures and primary generalized tonic-clonic seizures. It is available in both oral (tablet, solution) and injectable form. There are different types of seizures, with different sets of symptoms and treatments, including drugs such as lacosamide (Vimpat). Drugs typically are used to prevent or control seizures, and can be used by itself (monotherapy) or in combination (adjunctive) with other anticonvulsants. The right treatment, including drugs, depend on the seizure types and other patient-specific factors.

Definitions

"Seizure" is a sudden change in behavior caused by electrical hyperactivity of neuronal networks in the cerebral cortex of the brain.

"Partial-onset seizures" or "focal seizures" typically start in one side of the brain. Since some people who experience them may not even realize they are having a seizure, partial-onset seizures can be subtle and hard to identify.

"Generalized-onset seizures" or "grand mal seizures" involve both sides of the brain causing muscle stiffness and rhythmic jerking convulsions for several minutes. Loss of consciousness is common with this type of seizure.

Medical Necessity Criteria for Initial Authorization

The Plan considers <u>lacosamide (Vimpat)</u> medically necessary when the **ALL** the following criteria are met for the applicable indication listed below:

For the treatment of partial seizures

- 1. The requested medication is prescribed by or in consultation with a specialist with expertise in epilepsy management (e.g., neurologist); **AND**
- 2. The member is one (1) month of age or older; AND
- 3. The member has a diagnosis of focal (partial) onset seizures; AND
- 4. The member is unable to use or has adequately tried and failed at least a one-month trial to **TWO** (2) of the following:
 - a. Carbamazepine; and/or
 - b. Divalproex sodium; and/or
 - c. gabapentin; and/or
 - d. Lamotrigine; and/or
 - e. Levetiracetam; and/or
 - f. Oxcarbazepine; and/or
 - q. Phenobarbital; and/or
 - h. Phenytoin; and/or
 - i. Pregabalin; and/or
 - j. Topiramate; and/or
 - k. Valproic acid; and/or
 - I. Zonisamide; AND
- Clinical chart documentation is provided for review to substantiate the above listed requirements.

For the treatment of generalized tonic-clonic seizures

- 1. The requested medication is prescribed by or in consultation with a specialist with expertise in epilepsy management (e.g., neurologist); **AND**
- 2. The member is 4 years of age or older; AND
- 3. The member has a diagnosis of primary generalized tonic-clonic seizures; AND
- 4. The member is unable to use or has adequately tried and failed at least a one-month trial to **TWO** (2) of the following:
 - a. Carbamazepine; and/or
 - b. Divalproex sodium; and/or
 - c. Lamotrigine; and/or
 - d. Levetiracetam; and/or
 - e. Phenobarbital; and/or
 - f. Phenytoin; and/or
 - g. Topiramate; and/or
 - h. Valproic acid; AND
- 5. Lacosamide (Vimpat) is being used in combination with other anticonvulsants; AND
- 6. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, lacosamide (Vimpat) will be approved for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if recent (within the last 12 months) clinical chart documentation is provided showing that the member has experienced clinical improvement in symptoms since starting the requested medication as evidenced by a reduction in severity and/or frequency of seizures.

Experimental or Investigational / Not Medically Necessary

Lacosamide (Vimpat) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Acute Kidney Injury (AKI)
- Alcohol Use Disorders (AUD)

- Amyotrophic Lateral Sclerosis (ALS)
- Anxiety Disorders
- Avascular Necrosis
- Chronic Abdominal Pain (CAP)
- Chronic Pain, Chronic Pain Syndrome
- Dementia
- Depression
- Diabetic Neuropathies, Painful Diabetic Neuropathy (PDN)
- Fibromyalgia
- Migraine
- Neuropathic Pain
- Opioid Dependence, Opioid Related Disorders, Opioid Use Disorder (OUD)
- Osteoarthritis (OA)
- Postherpetic Neuralgia
- Psychosomatic Disorders
- Rheumatoid Arthritis
- Schizophrenia
- Sciatica
- Small Fibre Neuropathy

References

- 1. Brophy GM, Bell R, Claassen J, et al; Neurocritical Care Society Status Epilepticus Guideline Writing Committee. Guidelines for the evaluation and management of status epilepticus. Neurocrit Care. 2012;17(1):3-23.
- 2. Farrokh S, Bon J, Erdman M, Tesoro E. Use of newer anticonvulsants for the treatment of status epilepticus. Pharmacotherapy. 2019;39(3):297-316. doi:10.1002/phar.2229
- 3. Holtkamp D, Opitz T, Niespodziany I, et al. Activity of the anticonvulsant lacosamide in experimental and human epilepsy via selective effects on slow Na(+) channel inactivation. Epilepsia 2017; 58:27.
- 4. Jirsch J, Hirsch LJ. Nonconvulsive status epilepticus: Classification, clinical features, and diagnosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 28, 2022.
- 5. Kanner AM, Ashman E, Gloss D, Harden C, Bet al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the American Epilepsy Society and the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Epilepsy Curr. 2018 Jul-Aug;18(4):269-278. doi: 10.5698/1535-7597.18.4.269. PMID: 30254528; PMCID: PMC6145395.
- 6. Motpoly XR (lacosamide) injection, oral solution, tablet [prescribing information]. Piscataway, NJ: Aucta Pharmaceuticals Inc; June 2024.

- 7. Ortiz de la Rosa JS, Ladino LD, Rodríguez PJ, Rueda MC, Polanía JP, Castañeda AC. Efficacy of lacosamide in children and adolescents with drug-resistant epilepsy and refractory status epilepticus: a systematic review. Seizure. 2018;56:34-40. doi:10.1016/j.seizure.2018.01.014
- 8. Perucca E, Yasothan U, Clincke G, Kirkpatrick P. Lacosamide. Nat Rev Drug Discov 2008; 7:973.
- 9. Price R, Smith D, Franklin G, Gronseth G, Pignone M, David WS, Armon C, Perkins BA, Bril V, Rae-Grant A, Halperin J, Licking N, O'Brien MD, Wessels SR, MacGregor LC, Fink K, Harkless LB, Colbert L, Callaghan BC. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary: Report of the AAN Guideline Subcommittee. Neurology. 2022 Jan 4;98(1):31-43. doi: 10.1212/WNL.000000000013038. PMID: 34965987.
- 10. Strzelczyk A, Zöllner JP, Willems LM, et al. Lacosamide in status epilepticus: systematic review of current evidence. Epilepsia. 2017;58(6):933-950. doi:10.1111/epi.13716
- 11. Verrotti A, Loiacono G, Pizzolorusso A, et al. Lacosamide in pediatric and adult patients: comparison of efficacy and safety. Seizure. 2013;22(3):210-216.
- 12. Vimpat (lacosamide) injection, oral solution, tablet [prescribing information]. Smyrna, GA: UCB Inc; October 2023.
- 13. Vimpat (lacosamide) injection, oral solution, tablet [prescribing information]. Smyrna, GA: UCB Inc; April 2023.
- 14. Vossler DG, Bainbridge JL, Boggs JG, et al. Treatment of refractory convulsive status epilepticus: a comprehensive review by the American Epilepsy Society Treatments Committee. Epilepsy Curr. 2020;20(5):245-264. doi:10.1177/1535759720928269
- 15. Wechsler RT, Li G, French J, et al. Conversion to lacosamide monotherapy in the treatment of focal epilepsy: results from a historical-controlled, multicenter, double-blind study. Epilepsia. 2014;55(7):1088-1098. doi:10.1111/epi.12681

Clinical Guideline Revision / History Information

Original Date: 11/05/2020

Reviewed/Revised: 10/14/2021, 12/01/2021, 9/15/2022, 9/21/2023, 12/19/2024