Lacosamide (Vimpat)

Summary

Partial-onset seizures, also known as focal seizures, start in a specific area or 'focus' in the brain. There are several subtypes of focal seizures including: focal aware seizures, focal impaired awareness seizures, focal motor seizures, focal nonmotor seizures and focal bilateral tonic-clonic seizures. The specific symptoms of a partial-onset seizure can vary widely depending on the area of the brain where the seizure originates. Focal epilepsy may be due to a focal brain pathology (due to a known syndrome or genetic cause), or be due to an unknown cause. Focal seizures can be managed with both narrow spectrum (e.g., carbamazepine, gabapentin, oxcarbazepine, phenytoin, phenobarbital, primidone, tiagabine) and broad spectrum anti-seizure medications (e.g., Briviact [brivaracetam], clobazam [Onfi], felbamate [Felbatol], lamotrigine (Lamictal), levetiracetam [Keppra], valproate, zonisamide [Zonegran]) including lacosamide [Vimpat]).

Generalized tonic-clonic seizures begin with a loss of consciousness and limb stiffness (tonic phase), and move into the clonic phase as their muscles jerk and twitch. Occasionally a tonic-clonic seizure may result from a focal-onset seizure. Generalized tonic-clonic seizures are managed primarily with broad spectrum antiseizure medications.

Lacosamide (Vimpat) is an anticonvulsant indicated for the treatment of partial-onset seizures (in those 1 month of age and older) and primary generalized tonic-clonic seizures (in those 4 years of age and older). It is available in both oral (tablet, solution) and injectable form.

Definitions

"Epilepsy" is a neurological disorder characterized by recurrent, unprovoked seizures. The diagnosis typically applies when a person experiences two or more seizures that occur more than 24 hours apart and are not caused by a known and reversible medical condition such as alcohol withdrawal or extremely low blood sugar.

"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.

"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.

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

Medical Necessity Criteria for Initial Authorization

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

For the treatment of partial-onset (focal) seizures

1. The member is one (1) month of age or older; *AND*
2. The member has a diagnosis of focal seizures (partial-onset, partial seizures); *AND*
3. The member is unable to use or has adequately tried and failed at least TWO (2) of the following:
    a. Carbamazepine*; and/or*
    b. Divalproex sodium (use in those 9 years of age and younger is off-label)*; and/or*
    c. Fosphenytoin; *and/or*
    d. gabapentin*; and/or*
    e. Lamotrigine*; and/or*
    f. Levetiracetam*; and/or*
    g. Methsuximide; *and/or*
    h. Oxcarbazepine*; and/or*
    i. Phenobarbital*; and/or*
    j. Phenytoin*; and/or*

k. Pregabalin*; and/or*
l. Primidone; *and/or*
m. Tiagabine (use in those 11 years of age and younger is off-label); and/or
n. Topiramate*; and/or*
o. Valproate (use in those 9 years of age and younger is off-label); *and/or*
p. Valproic acid (use in those 9 years of age and younger is off-label)*; and/or*
q. Zonisamide (use in those 15 years of age and younger is off-label); *AND*

4. Clinical chart documentation is provided for review to substantiate the above listed requirements.

<u>For the treatment of generalized tonic-clonic seizures</u>

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 TWO (2) of the following:
    a. Carbamazepine*; and/or*
    b. Divalproex sodium (use in those 9 years of age and younger is off-label)*; 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 (use in those 9 years of age and younger is off-label); *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.

<u>If the above prior authorization criteria are met, lacosamide (Vimpat) will be approved for up to a lifetime.</u>

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). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of AKI.

- Alcohol Use Disorders (AUD). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of AUD outside of seizure management.
- Amyotrophic Lateral Sclerosis (ALS). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of ALS.
- Anxiety Disorders. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of anxiety.
- Avascular Necrosis. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of avascular necrosis.
- Chronic Abdominal Pain (CAP). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of CAP. In 2024 a protocol for a phase 1 study was published to assess the role of lacosamide (Vimpat) for the use in painful chronic pancreatitis.
- Chronic Pain, Chronic Pain Syndrome. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of chronic pain syndrome.
- Dementia. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of dementia outside of seizure management.
- Depression. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of depression outside of the management of co-morbid seizures.
- Diabetic Neuropathies, Painful Diabetic Neuropathy (PDN). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of PDN.
- Fibromyalgia. Based on four Cochrane reviews found insufficient evidence and data to evaluate the effectiveness of lacosamide (Vimpat) for the management of fibromyalgia.
- Migraine. Only one randomized trial of 200 participants with episodic migraines found that lacosamide was more effective than placebo at reducing the frequency and duration of migraine attacks. However, the study was open-label and completed in one facility which limited generalizability.
- Neuropathic Pain. Only one randomized controlled trial studied the use of lacosamide (Vimpat) for the management of peripheral neuropathy, however the study was terminated early due to poor efficacy of lacosamide (Vimpat) compared to placebo in a small study group (n=49 fulfilling per protocol criteria).
- Opioid Dependence, Opioid Related Disorders, Opioid Use Disorder (OUD). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of OUD.
- Osteoarthritis (OA). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of OA.
- Postherpetic Neuralgia. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of postherpetic neuralgia.
- Psychosomatic Disorders. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of psychosomatic disorders.
- Rheumatoid Arthritis (RA). There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of RA.

- Schizophrenia. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of schizophrenia.
- Sciatica. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of sciatica.
- Small Fibre Neuropathy. There are no high-quality studies to support the safety and efficacy of lacosamide (Vimpat) for the management of small fibre neuropathy.

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