lamotrigine extended release (Lamictal XR)

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

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 medication (e.g., Briviact [brivaracetam], clobazam, felbamate, lacosamide, lamotrigine, levetiracetam, valproate, zonisamide) including lamotrigine .

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.

Lennox-Gastaut syndrome (LGS) is a lifelong epileptic encephalopathy, causing chronic seizures and intellectual disability which presents in childhood. First-line management of LGS is typically valproate, however many require additional anti-seizure medications including lamotrigine, rufinamide, topiramate, clobazam, felbamate, and fenfluramine.

Absence seizures are a form of seizures that are characterized by their frequent (multiple daily seizure) and short presentation where consciousness is impaired. They rarely present with body tone loss, and are often undiagnosed due to the subtle symptoms. Absence seizures are generally managed with ethosuximide, however second-line therapy includes lamotrigine and valproate, and less commonly topiramate, benzodiazepines, and zonisamide.

Bipolar disorder is a mental health condition characterized by symptoms of mania (elevated or irritable mood, increased activity and energy), hypomania (elevated mood, energy and activity less severe than mania episodes), or major depression (low mood, lack of interest in activities) and mania. Bipolar disorder can often be accompanied by psychotic features (e.g., delusions and hallucinations), especially in the case of mania or bipolar major depression. These episodes can impact a person's ability to function in daily life due to their severity and unpredictability. Therapy is tailored to the individual and their responses to prior therapies. First-line pharmacotherapy typically includes vaproate, divalproex, and lithium; second-line therapies include quetiapine and lamotrigine; third-line therapies may include antipsychotics (e.g., risperidone, aripiprazole, olanzapine).

Trigeminal neuralgia is a type of neuropathic pain (stabbing, intensense, burning pain) that affects one or more branches of the trigeminal nerve of the face and head. Therapies typically include pharmacotherapy such as cabamazepine, oxcarbazepine, gabapentin, lamotrigine or baclofen; rescue therapies, such as injectable agents (e.g., lidocaine, sumatriptan, phenytoin); and in rare cases, surgical interventions.

Short-lasting unilateral neuralgiform headaches attacks refers to a rare headache disorder characterized by brief, severe, and recurrent attacks of pain (burning, stabbing, or electrical in nature) on one side of the head. It is sometimes accompanied by conjunctival injection (redness of the eye) and/or tearing. In the short-term, these attacks can be managed with intravenous lidocaine; however, long-term preventative therapy can include lamotrigine, topiramate, or gabapentin.

Lamotrigine is an oral anticonvulsant medication that has received FDA approval for its application in managing bipolar disorder, Lennox-Gastaut syndrome, focal (also known as partial-onset) seizures, and generalized tonic-clonic seizures. The precise mechanism underlying its anticonvulsant activity is not entirely understood. However, research suggests that lamotrigine may stabilize neuronal membranes by acting on voltage-sensitive sodium channels, thereby inhibiting the release of glutamate and aspartate, two excitatory amino acids.

Lamotrigine is available in multiple oral dosage formulations: extended-release (ER) and immediate-release (IR) tablets, orally disintegrating tablets (ODTs) and chewable tablets. The ER tablets have only been studied in those 12 years of age and older (13 years of age and older for the indication of seizures), while the IR and ODT formulations have been studied in those as young as 2 years of age.

Lamotrigine carries a boxed warning for the risk of serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis. The risk of serious rash is greater in pediatrics than in adults. To prevent the development of rash, a serious potential side effect, lamotrigine requires a slow and careful dosage titration. Compared to traditional antiepileptic drugs, lamotrigine is generally less sedating and produces fewer cognitive adverse effects. Its use as a monotherapy is associated with one of the lowest teratogenicity rates, making it a preferred choice for female patients of childbearing potential.

Definitions

“Anti-epileptics” refers to medications used to treat seizures.

"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.

"Bipolar Disorder" is a mental health condition marked by significant mood swings that alternate between periods of depression (low mood, lack of interest in activities) and mania (elevated or irritable mood, increased activity and energy). These episodes can impact a person's ability to function in daily life due to their severity and unpredictability.

"Lennox-Gastaut syndrome" is a rare and severe form of epilepsy that starts in childhood, characterized by multiple types of seizures and intellectual disability.

"Focal (Partial) Seizures" refers to seizures that start in, and affect, just one part of the brain. They can sometimes spread to wider areas on the same side of the brain.

"Generalized Tonic-Clonic Seizures," formerly known as grand mal seizures, involve the whole body and typically include a period of muscle rigidity (the "tonic" phase) followed by rhythmic muscle contractions (the "clonic" phase).

“Short-lasting unilateral neuralgiform headaches attacks” refers to a rare headache disorder characterized by brief, severe, and recurrent attacks of pain (burning, stabbing, or electrical in nature) on one side of the head. It is accompanied by conjunctival injection (redness of the eye) and/or tearing.

"Teratogenicity" is the capability of a drug or other substance to cause birth defects.

"Trigeminal neuralgia" is a type of neuropathic pain (stabbing, intensense, burning pain) that affects one or more branches of the trigeminal nerve of the face and head.

Medical Necessity Criteria for Authorization

The Plan considers lamotrigine extended-release (ER) medically necessary when ALL the criteria are met for ONE of the following diagnoses:

For management of seizure disorders

1. The member is 13 years of age or older; *AND*
2. The member has a documented diagnosis of epilepsy or seizure disorder*; AND*
3. The member is unable to use, or has adequately tried and failed ONE of the following for at least a ONE (1) month duration:
    a. Carbamazepine; *or*
    b. Divalproex; *or*
    c. Ethosuximide; *or*
    d. Lacosamide; *or*
    e. Lamotrigine immediate-release; *or*
    f. Levetiracetam; *or*
    g. Methsuximide; *or*
    h. Oxcarbazepine; *or*
    i. Phenobarbital; *or*
    j. Phenytoin; *or*
    k. Pregabalin; *or*
    l. Primidone; *or*
    m. Tiagabine; *or*
    n. Topiramate; *or*
    o. Valproate; *or*
    p. Valproic acid; or
    q. Zonisamide (use in those 15 years of age and younger is off-label); *AND*
4. Lamotrigine ER is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature*; AND*
    a. Clinical chart documentation is provided for review to substantiate the above listed requirements.

For the treatment of bipolar disorder

1. The member is 12 years of age or older; *AND*
2. The member has a documented diagnosis of bipolar disorder*; AND*
3. The member is unable to use, or has adequately tried and failed lamotrigine immediate-release for at least a ONE (1) month duration; *AND*
4. Lamotrigine ER is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature*; AND*
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met for the applicable indication, Lamotrigine ER will be approved for the member's lifetime.

Experimental or Investigational / Not Medically Necessary

Lamotrigine ER for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

Original Date: 11/05/2020

Reviewed/Revised: 10/14/2021, 12/01/2021, 06/23/2022, 06/29/2023, 12/19/2024, 12/01/2025