Oscar Clinical Guideline: lamotrigine extended release (Lamictal XR) (PG055, Ver. 5)

lamotrigine extended release (Lamictal XR)

Summary

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) 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 neurotransmitters.

Lamotrigine is available in two oral formulations: extended-release (ER) and immediate-release (IR). 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

"**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).

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

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. Lamotrigine immediate release**; *or***
e. Levetiracetam**; *or***
f. Oxcarbazepine**; *or***
g. Phenobarbital**; *or***
h. Phenytoin**; *or***
i. Topiramate**; *or***
j. Valproate**; *or***
k. Valproic acid

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

If the above prior authorization criteria are met for the applicable indication, Lamotrigine ER will be approved for 12 months.

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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