

Specialty Guideline Management

Firdapse

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Firdapse	amifampridine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Firdapse is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of either of the following diagnostic tests is necessary to initiate the prior authorization review:

- Electromyography (EMG)
- Anti-P/Q type voltage-gated calcium channel antibody test

Exclusions

Coverage will not be provided for members with a history of seizures.

Coverage Criteria

Lambert-Eaton Myasthenic Syndrome (LEMS)

Authorization of 6 months may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS) when all of the following criteria are met:

- Diagnosis is confirmed by either of the following:
 - EMG showing compound muscle action potential (CMAP) that increased at least 2-fold after maximum voluntary contraction of the tested muscle.
 - A positive anti-P/Q type voltage-gated calcium channel antibody test.
- Member has proximal muscle weakness.
- For treatment-naïve members, the Quantitative Myasthenia Gravis (QMG) score is at least 5.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for LEMS who are responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

References

1. Firdapse [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; May 2024.
2. Oh SJ, Scherbakova N, Kostera-Pruszczyk A, et al; LEMS Study Group. Amifampridine phosphate (Firdapse®) is effective and safe in a phase 3 clinical trial in LEMS. *Muscle Nerve*. 2016;53(5):717-25. doi: 10.1002/mus.25070
3. Shieh P, Sharma K, Kohrman B, Oh SJ. Amifampridine phosphate (Firdapse) is effective in a confirmatory phase 3 clinical trial in LEMS. *J Clin Neuromuscul Dis*. 2019; 20(3):111-119. doi: 10.1097/CND.0000000000000239