

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Firdapse (amifampridine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes pyridostigmine QUANTITY LIMIT— 240 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Firdapse (amifampridine) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### LAMBERT-EATON MYASTHENIC SYNDROME (LEMS)

For **initial** authorization:

1. Member 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by documentation of diagnostic test results including one of the following:
  - a) Repetitive nerve stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise; AND
  - b) Positive anti-P/Q type voltage-gated calcium channel antibody test; AND
4. Member must have a documented baseline ECG in the last 12 months demonstrating QT interval < 450 milliseconds; AND
5. Member must have documented baseline Quantitative Myasthenia Gravis (QMG) testing; AND
6. Member does NOT have any of the following:
  - a) History of seizures;
  - b) Active brain metastases;
  - c) Unable to ambulate;
  - d) Currently pregnant or lactating.
7. **Dosage allowed:** The recommended starting dosage is 15 mg to 30 mg daily taken orally in divided doses (3 to 4 times daily); dosage can be increased by 5 mg daily every 3 to 4 days. Not to exceed 80 mg/day. The maximum single dose is 20 mg.

***If member meets all the requirements listed above, the medication will be approved for 3 months.***

For **reauthorization**:

1. Member meets all initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***



**CareSource considers Firdapse (amifampridine) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Myasthenia gravis (MG)

DATE	ACTION/DESCRIPTION
05/20/2019	New policy for Firdapse created.

References:

1. Firdapse (amifampridine) [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc. 2018 Nov.
2. ClinicalTrials.gov. Identifier: NCT02970162. Phase 3 study to evaluate efficacy of amifampridine phosphate in Lambert-Eaton myasthenic syndrome (LEMS). Available: [clinicaltrials.gov/ct2/show/NCT02970162](https://clinicaltrials.gov/ct2/show/NCT02970162).
3. ClinicalTrials.gov. Identifier: NCT01377922. Phase 3 study of amifampridine phosphate in patients with Lambert-Eaton myasthenic syndrome (LEMS). Available: [clinicaltrials.gov/ct2/show/NCT01377922](https://clinicaltrials.gov/ct2/show/NCT01377922).
4. Kesner VG, et al. Lambert-Eaton myasthenic syndrome. *Neurologic clinics*. 2018;36(2):379-394.
5. Harper MC, et al. Lambert-Eaton syndrome. *Myasthenia Gravis and Related Disorders*. Humana Press, Cham. 2018. 221-237.
6. Sanders DB, et al. 3, 4-diaminopyridine base effectively treats the weakness of Lambert-Eaton myasthenia. *Muscle & nerve*. 2018;57(4):561-568.
7. Khadilkar SV, et al. Lambert–Eaton Myasthenic Syndrome. *Neuromuscular Disorders*. Springer, Singapore. 2018. 261-272.
8. Schoser B, et al. Amifampridine Phosphate in patients with Lambert-eaton myasthenic syndrome (lems): a phase 3, multicentre, double-blind, placebo-controlled trial: p31181. *European Journal of Neurology*. 2016;23: 690-691.
9. Oh SJ, et al. Amifampridine phosphate (Firdapse®) is effective and safe in a phase 3 clinical trial in LEMS. *Muscle & nerve*. 2016;53(5):717-725.

Effective date: 07/01/2019

Revised date: 05/20/2019