CareSource

PHARMACY POLICY STATEMENT **Indiana 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 **NOT** MEDICALLY NECESSARY	Click Here

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.
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.
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: 10/01/2019
Revised date: 05/20/2019