CareSource

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: 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 is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist or oncologist; AND
3. Member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by documentation of at least 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; or
   b) Positive anti-P/Q type voltage-gated calcium channel antibody test; AND
4. Member has progressive proximal muscle weakness; AND
5. Member does not have a history of seizures; AND
6. Clinically significant reason why Ruzurgi cannot be used (e.g. documented allergy to inactive ingredient not found in Firdapse).
7. **Dosage allowed:** Initial, 15 mg to 30 mg/day orally as 3 or 4 divided doses; may increase by 5 mg/day every 3 to 4 days; max single dose 20 mg; max total dose/day 80mg.

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

For **reauthorization**:

1. Chart notes must document improved muscle strength.

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.
04/27/2021	Updated references. Added oncology as specialist. Changed diagnostic criteria from “and” to “or.” Removed baseline ECG. Removed baseline QMG. Added muscle weakness (symptomatic). Added preference for Ruzurgi. Abbreviated dosing information. Removed restrictions except for seizure. Revised renewal criteria.

References:

1. Firdapse (amifampridine) [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc; March 2021.
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. 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.
6. Titulaer MJ, Lang B, Verschuuren JJ. Lambert-Eaton myasthenic syndrome: from clinical characteristics to therapeutic strategies. *Lancet Neurol*. 2011;10(12):1098-1107. doi:10.1016/S1474-4422(11)70245-9
7. Schoser B, Eymard B, Datt J, Mantegazza R. Lambert-Eaton myasthenic syndrome (LEMS): a rare autoimmune presynaptic disorder often associated with cancer [published correction appears in J Neurol. 2017 Jul 10;:]. *J Neurol*. 2017;264(9):1854-1863. doi:10.1007/s00415-017-8541-9

Effective date: 10/1/2021
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