CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Firdapse (amifampridine)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Firdapse was approved in 2018 for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. LEMS is a rare autoimmune disorder of the neuromuscular junction. Autoantibodies damage the motor nerve membrane leading to reduced release of acetylcholine. This results in muscle weakness, fatigue, and other symptoms. Many patients with LEMS are also found to have small cell lung cancer (SCLC). Firdapse is a potassium channel blocker. It helps improve the release of acetylcholine.

Firdapse (amifampridine) will be considered for coverage when the following criteria are met:

Lambert-Eaton Myasthenic Syndrome (LEMS)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a neurologist or oncologist; AND
2. 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
3. Member has progressive proximal muscle weakness; AND
4. Member does not have a history of seizures.
5. **Dosage allowed/Quantity limit:** 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. (Limit 240 tablets per 30 days).
   NOTE: Use of Firdapse in patients younger than 18 years of age is off-label. LEMS in pediatric patients is extremely rare.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must document improved muscle strength.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Firdapse (amifampridine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
02/08/2022	Transferred to new template. Removed trial of Ruzurgi (withdrawn from market following patent lawsuit). Removed age limit and added note about off label use under age 18 (Ruzurgi was approved for age 6-17 years and is the same drug).

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: 07/01/2022
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