HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Firdapse (amifampridine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Firdapse, initially approved by the FDA in 2018, is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older. 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 (amifampridine) will be considered for coverage when the following criteria are met:

Lambert-Eaton Myasthenic Syndrome (LEMS)

For **initial** authorization:

1. Member is at least 6 years of age; 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) study abnormalities;
   b) Positive anti-P/Q type voltage-gated calcium channel antibody test; AND
4. Member has progressive proximal muscle weakness; AND
5. Provider attests member does not have a history of seizures.
6. **Dosage allowed/Quantity limit:** See table below. Quantity limit: 10 tablets per day

Age and Body Weight	Initial Daily Dosage	Titration Regimen	Maximum Single Dose	Maximum Total Daily Maintenance Dose
• Adults • Pediatric patients weighing 45 kg or more	15 mg to 30 mg daily in 3 to 5 divided doses	Increase total daily dosage by 5 mg every 3 or 4 days	20 mg	100 mg given in divided doses
• Pediatric patients weighing less than 45 kg	5 mg to 15 mg daily in 3 to 5 divided doses	Increase total daily dosage by 2.5 mg every 3 or 4 days	10 mg	50 mg given in divided doses

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

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For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease documented by improved muscle strength.

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

HAP 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).
11/02/2022	Added age limit and updated dosing in accordance with labeling changes.
10/17/2024	Updated adult dosing and quantity limit; added provider attestation to existing criteria of no history of seizures; simplified RNS study requirement.

References:

1. Firdapse (amifampridine) [prescribing information]. Catalyst Pharmaceuticals, Inc; 2024.
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3. Kesner VG, et al. Lambert-Eaton myasthenic syndrome. Neurologic clinics. 2018;36(2):379-394.
4. 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.
5. 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
6. 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
7. Wiendl H, Abicht A, Chan A, et al. Guideline for the management of myasthenic syndromes [published correction appears in Ther Adv Neurol Disord. 2024 Apr 30;17:17562864241246400. doi: 10.1177/17562864241246400]. *Ther Adv Neurol Disord.* 2023;16:17562864231213240. Published 2023 Dec 26. doi:10.1177/17562864231213240

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