CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Ruzurgi (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— 300 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ruzurgi (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 6 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.
6. **Dosage allowed:**
   Weight less than 45 kg: Initial, 7.5 mg to 15 mg/day in 2-3 divided doses; may increase daily in 2.5 mg to 5 mg increments, divided in up to 5 doses per day; max 15 mg per dose and 50 mg per day.
   Weight 45 kg or more: Initial, 15 mg to 30 mg/day in 2-3 divided doses; may increase daily in 5 mg to 10 mg increments, divided in up to 5 doses per day; max 30 mg per dose and 100 mg per day.

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 Ruzurgi (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
11/13/2019	New policy for Ruzurgi created.
04/28/2021	Updated references. Added oncology as specialist. Changed diagnostic criteria from “and” to “or.” Removed baseline ECG. Added muscle weakness (symptomatic). Abbreviated dosing information. Removed restrictions except for seizure. Revised renewal criteria. Corrected quantity limit.

References:

1. Ruzurgi (amifampridine) [prescribing information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc; April 2020.
2. ClinicalTrials.gov. Identifier: NCT: 01511978. Effectiveness of 3,4-Diaminopyridine in Lambert-Eaton Myasthenic Syndrome (DAPPER). Available: https://clinicaltrials.gov/ct2/show/NCT01511978?term=NCT%3A+01511978&draw=1&rank=1.
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

Effective date: 01/01/2022
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