

## PHARMACY POLICY STATEMENT

### Arkansas PASSE

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 includes pyridostigmine QUANTITY LIMIT— 240 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Ruzurgi (amifampridine) 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 6 years of age or older; AND
2. 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
3. Member does NOT have any of the following:
  - a) History of seizures;
  - b) Currently pregnant or lactating.
4. **Dosage allowed:** Weigh 45 kg or more: Initial dosage is 15 mg to 30 mg daily, in divided doses. Increase daily in 5 mg to 10 mg increments, divided in up to 5 doses daily. Maximum single dose is 30 mg; maximum daily dosage is 100 mg. Weigh less than 45 kg: Initial dosage is 7.5 mg to 15 mg daily, in divided doses. Increase daily in 2.5 mg to 5 mg increments, divided in up to 5 doses daily. Maximum single dose is 15 mg; maximum daily dosage is 50 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 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.
12/22/2021	Removed prescriber specialty requirement, ECG requirement, and documentation that member does not have active brain metastases or unable to ambulate.

References:

1. Ruzurgi (amifampridine) [prescribing information]. Plainsboro, NJ: Jacobus Pharmaceutical Company, Inc; May 2019.
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. Harper MC, et al. Lambert-Eaton syndrome. Myasthenia Gravis and Related Disorders. Humana Press, Cham. 2018. 221-237.
5. Sanders DB, et al. 3, 4-diaminopyridine base effectively treats the weakness of Lambert-Eaton myasthenia. Muscle & nerve. 2018;57(4):561-568.
6. Khadilkar SV, et al. Lambert–Eaton Myasthenic Syndrome. Neuromuscular Disorders. Springer, Singapore. 2018. 261-272.
7. 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.
8. 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.
9. Mantegazza, Renato. "Amifampridine tablets for the treatment of Lambert-Eaton myasthenic syndrome." Expert review of clinical pharmacology (2019): 1-6.
10. Oh, SJ. "Amifampridine for the treatment of Lambert-Eaton myasthenic syndrome." Expert review of clinical immunology 15.10 (2019): 991-1007.

Effective date: 01/01/2022

Revised date: 12/22/2021