CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
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 **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 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. 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
4. Member must have a documented baseline ECG in the last 12 months demonstrating QT interval < 450 milliseconds; AND
5. Member does NOT have any of the following:
   a) History of seizures;
   b) Active brain metastases;
   c) Unable to ambulate;
   d) Currently pregnant or lactating.
6. **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.

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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.

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: 04/01/2020
Revised date: 11/13/2019