ALASKA MEDICAID Prior Authorization Criteria

Firdapse®, Ruzurgi® (amifampridine)

FDA INDICATIONS AND USAGE^{1,2}

Firdapse® and Ruzurgi® are a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS). Ruzurgi® is only indicated for patients age 6 to less than 17 years of age and FIRDAPSE® is only indicated for adult patients.

APPROVAL CRITERIA^{1,2,3}

- 1. For Ruzurgi® the patient is between 6 and less than 17 years of age or for Firdapse® the patient is 6 years of age or older **AND**;
- 2. Patient has the diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) AND;
- 3. Prescribed by or in consultation of a neurologist or neuromuscular specialist **AND**;
- 4. Patient does not have a history of seizures AND;
- 5. Prescriber agrees to monitor for use with acetylcholinesterase inhibitors or other medication that can lower seizure threshold **AND**;
- 6. Patient has moderate to severe weakness that that interferes with daily functions.

DENIAL CRITERIA^{1,2,3}

1. Failure to meet approval criteria.

CAUTIONS^{1,2}

- Can cause paresthesia/dysesthesia, abdominal pain, dyspepsia, dizziness, and nausea.
- Consider discontinuation or dose reduction for patients that have a seizure while on treatment.
- The concomitant use of drugs that lower seizure threshold may lead to an increased risk of seizures.
- Concomitant use of drugs with cholinergic effects can increase the risk of adverse reactions.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months if the patient is responding positively based on clinical muscle strength and the patient hasn't had any seizures.

OUANTITY LIMITS

- Ruzurgi® 10 tablets per day. Max daily dose 100mg.
- Firdapse® 8 tablets per day. Max daily dose 80mg.

Firdapse®, Ruzurgi® Criteria

Version: 2

Original: 10/3/2019 Approval: 11/18/2022 Effective: 1/2/2023

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REFERENCES / FOOTNOTES:

- 1. Ruzurgi® [prescribing information]. Princeton, NJ. Jacobus Pharmaceutical Company Inc. May 2019.
- 2. Firdapse® tablets [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; November 2018.
- 3. Kesner VG, Oh SJ, Dimachkie MM, et al. Lambert-Eaton Myasthenic Syndrome. Neurol Clin. 2018;36(2):379-394.

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