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 18 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. For Ruzurgi® the patient is not between 6 and 17 years of age or for FIRDAPSE® the patient is less than 18 years of age **OR**;
2. Patient does not have the diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) **OR**;
3. Medications are not being prescribed by or in consultation of a neurologist or neuromuscular specialist **OR**;
4. Patient has a history of seizures **OR**;
5. Prescriber does not agree to monitor for use with acetylcholinesterase inhibitors or other medication that can lower seizure threshold **OR**;
6. Patient does not have moderate to severe weakness that that interferes with daily functions.

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.

QUANTITY LIMITS

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

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.