

## Commercial/Healthcare Exchange PA Criteria

*Effective: May 8<sup>th</sup>, 2019*

**Prior Authorization:** Firdapse - Ruzurgi

**Products Affected:** Firdapse (amiframpridine) oral tablets; Ruzurgi (amiframpridine) oral tablets

**Medication Description:** Amiframpridine is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

**Covered Uses:** Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults (Firdapse) and children ages 6 to < 17 years of age (Ruzurgi).

**Exclusion Criteria:**

1. Patients with a history of seizures
2. Hypersensitivity to amifampridine or another aminopyridine

**Required Medical Information:**

1. Diagnosis
2. Medical History
3. Previous therapies tried/failed

**Age Restrictions:**

Firdapse – 18 years of age and older (adults)  
Ruzurgi – 6 years of age and older

**Prescriber Restrictions:** Prescribed by or in consultation with a neurologist or a neuromuscular specialist.

**Coverage Duration:**

Initial approval: 6 months, Continuation: 1 year

**Other Criteria:**

**Initial**

- A. Patient has confirmed Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels antibody testing.

**Continuation**

- A. Patient has demonstrated response to therapy with the addition of Firdapse/Ruzurgi (e.g., improved muscle strength, improvements in mobility).

**References:**

1. Firdapse® tablets [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; November 2018.
2. FDA news release. FDA approves first treatment for Lambert-Eaton myasthenic syndrome, a rare autoimmune disorder. Issued on: November 28, 2018. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm627093.htm>.
3. Kesner VG, Oh SJ, Dimachkie MM, et al. Lambert-Eaton Myasthenic Syndrome. *Neurol Clin.* 2018;36(2):379-394.
4. Oh S, Shcherbakova N, Kostera-Pruszczyk A, et al. Amifampridine phosphate (Firdapse®) is effective and safe in a phase 3 clinical trial in LEMS. *Muscle Nerve.* 2016;53(5):717-25.
5. Product Information: RUZURGI(R) oral tablets, amifampridine oral tablets. Jacobus Pharmaceutical Company Inc (per FDA), Plainsboro, NJ, 2019.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	4/23/2019
2	Update	Added Ruzurgi to Policy and all applicable criteria, Changed policy name	All	7/10/2019
3	Annual Review	N/A	N/A	3/30/2020

