Commercial/Healthcare Exchange PA Criteria

Effective: May 8th, 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

Rev #	Type of Change	Summary of Change	Sections Affected	Date
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