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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 14, 2018
Subject:	Firdapse Ruzurgi	**Page:**	1 of 4

Last Review Date: March 12, 2021

Firdapse Ruzurgi

Description

Firdapse, Ruzurgi (amifampridine)

Background
Firdapse (amifampridine) and Ruzurgi (amifampridine) are broad spectrum potassium channel blockers used to treat Lambert-Eaton myasthenic syndrome (LEMS). LEMS is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. LEMS may be associated with other autoimmune diseases, but more commonly occurs in patients with cancer such as small cell lung cancer, where its onset precedes or coincides with the diagnosis of cancer (1-3).

Regulatory Status
FDA-approved indication:

Firdapse is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults (1).

Ruzurgi is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age (2).

Firdapse and Ruzurgi can cause seizures. Seizures may be dose-dependent. The concomitant use of Firdapse and drugs that lower the seizure threshold may lead to an increased risk of seizures. Discontinuation or dose-reduction of Firdapse or Ruzurgi should be considered in patients who have a seizure while on treatment. Firdapse is contraindicated in patients with a history of seizures (1-2).

The safety and effectiveness of Firdapse in pediatric patients have not been established (1). The safety and effectiveness of Ruzurgi in pediatric patients below the age of 6 years have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Firdapse and Ruzurgi may be considered **medically necessary** in patients with Lambert-Eaton myasthenic syndrome (LEMS) and if the conditions indicated below are met.

Firdapse and Ruzurgi are considered **investigational** for all other indications.

Prior-Approval Requirements

Age **Firdapse only:** 18 years of age or older
Ruzurgi only: 6 to 16 years of age

Diagnosis

Patient must have the following:

Lambert-Eaton myasthenic syndrome (LEMS)

AND ALL of the following:

1. LEMS diagnosis confirmed using **ONE** of the following:
    a. Decreased amplitude of compound muscle action potential (CMAP) to a single supramaximal stimulus
    b. Positive autoantibody test against voltage-gated calcium channels (VGCC)
2. Patient does **NOT** have a history of seizures
3. Prescriber agrees to monitor for use with acetylcholinesterase inhibitors (which enhance the cholinergic effect of Firdapse/Ruzurgi) or other medications that can lower the seizure threshold

Prior – Approval *Renewal* Requirements

Age **Firdapse only:** 18 years of age or older
Ruzurgi only: 6 to 16 years of age

Diagnosis

Patient must have the following:

Lambert-Eaton myasthenic syndrome (LEMS)

AND ALL of the following:

1. Patient does **NOT** have a history of seizures
2. Prescriber agrees to monitor for use with acetylcholinesterase inhibitors or other medications that can lower the seizure threshold
3. Patient has a documented improvement since beginning therapy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Drug	Quantity
Ruzurgi	900 tablets per 90 days **OR**
Firdapse	720 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Firdapse (amifampridine) and Ruzurgi (amifampridine) are broad spectrum potassium channel blockers used to treat Lambert-Eaton myasthenic syndrome (LEMS). LEMS is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. LEMS may be associated with other autoimmune diseases, but more commonly occurs in patients with cancer such as small cell lung cancer, where its onset precedes or coincides with the diagnosis of cancer. The safety and effectiveness of Firdapse in pediatric patients have not been established. The safety and effectiveness of Ruzurgi in pediatric patients below the age of 6 years have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Firdapse and Ruzurgi while maintaining optimal therapeutic outcomes.

References

1. Firdapse [package insert]. Stamford, CT: Loxo Oncology, Inc.; November 2018.
2. Ruzurgi [package insert]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc.; April 2020.
3. Firdapse Press Announcement. FDA News Release. November 28, 2018. Accessed at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm627093.htm.

Policy History

Date	Action
December 2018	Addition to PA
March 2019	Annual review
May 2019	Addition of Ruzurgi. Renamed policy Firdapse Ruzurgi (amifampridine)
June 2019	Annual review. Added requirement of confirmed LEMS diagnosis using CMAP or antibody test per SME
September 2019	Annual review. Revised requirement for autoantibody test, prescriber agrees to monitor for use with acetylcholinesterase inhibitors which enhance the cholinergic effect of Firdapse/Ruzurgi, and documented improvement since starting therapy per SME
September 2020	Annual review and reference update
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.