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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 14, 2018
Subject:	Firdapse	**Page:**	1 of 4

Last Review Date: March 8, 2024

Firdapse

Description

Firdapse (amifampridine)

Background
Firdapse (amifampridine) is a broad-spectrum potassium channel blocker 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 (1-2).

Regulatory Status
FDA-approved indication: Firdapse is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adult and pediatric patients 6 years of age and older (1).

Firdapse 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 should be considered in patients who have a seizure while on treatment. Firdapse is contraindicated in patients with a history of seizures (1).

The safety and effectiveness of Firdapse in pediatric patients less than 6 years of age have not been established (1).

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 may be considered **medically necessary** if the conditions indicated below are met.

Firdapse may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 years of age or older

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. Positive autoantibody test against voltage-gated calcium channels (VGCC)
    b. Significant increased compound muscle action potential (CMAP) following high-frequency repetitive nerve stimulation (RNS) or evidence of post-exercise facilitation, characterized by enhanced deep tendon reflexes and muscle strength
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) or other medications that can lower the seizure threshold

Prior – Approval *Renewal* Requirements

Age 6 years of age or older

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
Firdapse	720 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Firdapse (amifampridine) is a broad-spectrum potassium channel blocker used to treat Lambert-Eaton myasthenic syndrome (LEMS). Firdapse can cause seizures so concomitant use with medications that lower the seizure threshold could increase the risk of seizures. The safety and effectiveness of Firdapse in pediatric patients less than 6 years of age have not been established (1).

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

References

1. Firdapse [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; May 2023.
2. Firdapse Press Announcement. FDA News Release. November 28, 2018. 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
March 2022	Annual review and reference update. Removed Ruzurgi from policy as the FDA approval was invalidated. Renamed policy Firdapse (amifampridine)
October 2022	Per PI update, reduced age requirement to 6 and older. Changed policy number to 5.57.026
December 2022	Annual review
March 2023	Annual review
September 2023	Annual review and reference update
December 2023	Annual review. Per SME, changed initiation requirement from decreased amplitude of CMAP to significant increased CMAP following high-frequency RNS or evidence of post-exercise facilitation, characterized by enhanced deep tendon reflexes and muscle strength
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.