Pharmacy Policy Bulletin: J-0859 Firdapse (amifampridine) – Commercial and Healthcare Reform	
Number: J-0859	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0859-009	**Original Date:** 01/30/2019
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Firdapse (amifampridine)
FDA-Approved Indication(s):	• Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older

Background:	• Firdapse is a broad-spectrum potassium channel blocker. The mechanism by which it exerts its therapeutic effect in LEMS patients is unknown.
	• LEMS is an autoimmune disease that is classified by the destruction of calcium channels at the neuromuscular junction of nerve cells, resulting in decreased release of acetylcholine. Low levels of acetylcholine at the neuromuscular junction lead to insufficient muscle contractions and muscle weakness.
	• LEMS is an orphan disease state with approximately 400 known cases in the United States.
	• Prescribing Considerations:
	  ○ Patients who are N-acetyltransferase 2 (NAT2) poor metabolizers should initiate treatment at the lowest recommended dose.
	  ○ Firdapse is contraindicated in patients with a history of seizures and patients with hypersensitivity to amifampridine or another aminopyridine.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Firdapse may be approved when the following criteria are met **(A. and B.)**:

A. The member is 6 years of age or older.

B. The member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10: G70.80, G70.81, G73.1) supported by one (1) of the following **(1. or 2.):**

1. Positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody testing

2. Neurophysiology studies characteristic of LEMS (e.g., high-frequency repetitive nerve stimulation)

II. Reauthorization

When a benefit, reauthorization of Firdapse may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy (e.g., improved muscle strength or mobility).

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Firdapse [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; May 2024.
2. Muscular Dystrophy Association. Lambert-Eaton Myasthenic Syndrome (LEMS). Available at: https://www.mda.org/disease/lambert-eaton-myasthenic-syndrome. Accessed November 2, 2022.
3. National Organization for Rare Disorders. Lambert-Eaton myasthenic syndrome. Available at: https://rarediseases.org/rare-diseases/lambert-eaton-myasthenic-syndrome/. Accessed November 2, 2022.