Clinical Policy: Amifampridine (Firdapse)

Reference Number: PA.CP.PHAR.411
Effective Date: 4.17.19
Last Review Date: 04.19

Revision Log

Description
Amifampridine (Firdapse®) is potassium channel blocker.

FDA Approved Indication(s)
Firdapse is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Firdapse is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Lambert-Eaton Myasthenic Syndrome (must meet all)**:**

1. Diagnosis of LEMS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Documentation of a baseline clinical muscle strength assessment (examples may include but are not limited to the Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW)) (see *Appendix D)*;
5. Dose does not exceed 80 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Lambert-Eaton Myasthenic Syndrome (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by clinical muscle strength assessments (examples may include but are not limited to the QMG score, 3TUG test, T25FW test) (see *Appendix D)*;
3. If request is for a dose increase, new dose does not exceed 80 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
LEMS: Lambert-Eaton myasthenic syndrome
QMG: Quantitative Myasthenia Gravis
3TUG: triple-timed up-and-go test
T25FW: Timed 25-foot Walk test

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of seizures; hypersensitivity to amifampridine or another aminopyridine
- Boxed warning(s): none reported

Appendix D: General Information

- QMG is a physician-rated evaluation consisting of 13 assessments of muscle function (e.g., swallowing, speech, forced vital capacity, movement of arms and legs). Each assessment is rated 0 to 3, where 0 indicates “no weakness” and 3 indicates “severe weakness” (lower scores reflect better muscle strength).
- The 3TUG is a functional mobility test that requires a patient to stand up from a straight-backed armchair, walk 3 meters, turn around, walk back, and sit down in the chair. Based upon literature reports that a significant change in gait for a similar walk-test is an increase in time of more than 20%, this was incorporated into the secondary endpoint used in the NCT02970162 clinical trial.
- The T25FW test, a component of the Multiple Sclerosis Functional Composite, is a quantitative mobility and leg function performance test based on a timed 25-foot walk. The patient was directed to walk a clearly marked 25-foot course as quickly and safely as possible. Following a period of rest, the timed 25-foot walk is repeated to determine an average score.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
LEMS	15 mg to 30 mg PO in 3 to 4 divided doses daily. Dose can be increased by 5 mg daily every 3 to 4 days. The maximum single dose is 20 mg.	80 mg/day

VI. Product Availability

Tablet: 10 mg

VII. References

1. Firdapse Prescribing Information. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; November 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208078s000lbl.pdf. Accessed December 13, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	