Effective date: 05/01/2022
Reviewed: 02/2022, 03/2023, 02/2024, 02/2025 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

FIRDAPSE (amifampridine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Firdapse is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years and older.

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for members with a history of seizures.

III. CRITERIA FOR INITIAL APPROVAL

Lambert-Eaton Myasthenic Syndrome (LEMS)
Authorization of 6 months may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS) in members 6 years and older when all of the following criteria are met:
A. The prescriber is a neurologist
B. Diagnosis is confirmed with documentation of one of the following:
    1. EMG showing compound muscle action potential (CMAP) that increased at least 2-fold after maximum voluntary contraction of the tested muscle
    2. A positive anti- P/Q type voltage-gated calcium channel antibody test
C. Documentation that the member has proximal muscle weakness
D. For treatment-naïve members, documentation of the Quantitative Myasthenia Gravis (QMG) score is at least 5

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members 6 years and older requesting reauthorization for LEMS who have documentation of responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

V. QUANTITY LIMIT

a. Firdapse 10mg: 10 tablets per day

VI. REFERENCES

1. Firdapse [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; September 2023.