Firdapse (amifampridine)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Firdapse policy is to encourage appropriate use according to clinical guidelines and/or clinical trials in the treatment of Lambert-Eaton myasthenic syndrome (LEMS).

The indications below including FDA-approved indications and compendial uses are considered covered benefits 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 of age and older.

POLICY

Documentation

Submission of either of the following diagnostic tests is necessary to initiate prior authorization review:

A. Electromyography (EMG)
B. Anti-P/Q type voltage-gated calcium channel antibody test

Exclusions

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

Criteria for Initial Approval

Lambert-Eaton Myasthenic Syndrome (LEMS)

Authorization of **6 months** may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS) when all the following criteria are met:

A. Diagnosis is confirmed by either 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
B. Member has proximal muscle weakness
C. For treatment-naïve members, the Quantitive Myasthenia Gravis (QMG) score is at least 5

Initial approval will be for **6 months**

Continuation of Therapy
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for LEMS whoare responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

Approval will be for **12 months**

Quantity Limits Apply
Firdapse 240 tablets/30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Firdapse [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; September 2022.
- A Phase 3 Study of Amifampridine Phosphate in Patients With Lambert Eaton Myasthenic Syndrome (LEMS). (2018). Retrieved from https://clinicaltrials.gov/ct2 (Identification No. NCT01377922)

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.54
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