Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Firdapse® (amifampridine)**

Effective: November 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Firdapse (amifampridine) is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Firdapse for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of Lambert-Eaton myasthenic syndrome

AND

2. The patient is 6 years of age or older

AND

3. Prescribed by or in consultation with a neurologist or neuromuscular specialist

AND

4. Documentation of moderate to severe weakness that interferes with daily function

AND

5. If malignancy is present, documentation of **one (1)** of the following:
    a. Underlying malignancy has been treated for at least three (3) months
    b. Patient has severe symptoms and malignancy is currently being treated
    c. The patient's malignancy is unable to be treated

Reauthorization Criteria

1. Documented diagnosis of Lambert-Eaton myasthenic syndrome

AND

2. The patient is 6 years of age or older

AND

3. Prescribed by or in consultation with a neurologist or neuromuscular specialist

AND

4. Documentation the patient has experienced a therapeutic response as defined by an improvement or stabilization in weakness and daily function from pretreatment baseline

AND

5. If malignancy is present, documentation of **one (1)** of the following:
    a. Underlying malignancy has been treated for at least three (3) months
    b. Patient has severe symptoms and malignancy is currently being treated
    c. The patient's malignancy is unable to be treated

Limitations

1. Initial approval by the plan will be limited to 6 months. Reauthorization will be provided in 12-month intervals.
2. Members new to the plan stable on Firdapse should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Firdapse (amifampridine) [prescribing information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; May 2023.
2. Lindquist S, Stangel M. Update on treatment options for Lambert-Eaton myasthenic syndrome: focus on use of amifampridine. Neuropsychiatr Dis Treat. 2011; 7:341-9.
3. Oh SJ, Shcherbakova N, Kostera-Pruszczyk A et al. Amifampridine phosphate (Firdapse(®)) is effective and safe in a phase 3 clinical trial in LEMS. Muscle Nerve. 2016; 53(5):717-25.
4. Schoser B, Eymard B, Datt J et al. Lambert-Eaton myasthenic syndrome (LEMS): a rare autoimmune presynaptic disorder often associated with cancer. J Neurol. 2017; 264(9):1854-1863

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- August 8, 2023: Added age requirements based on updated package labeling (effective 11/1/23).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.