Pharmacy Medical Necessity Guidelines: Amifampridine (Firdapse®, Ruzurgi®)

Effective: January 12, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

Ruzurgi (amifampridine) is a potassium channel blocker indicated for the treatment of LEMS in patients 6 to less than 17 years of age.

COVERAGE GUIDELINES

The plan may authorize coverage of Firdapse (amifampridine) or Ruzurgi (amifampridine) for Members, when all of the following criteria are met:

Initial Therapy

1. Documented diagnosis of Lambert-Eaton myasthenic syndrome

AND

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

AND

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

AND

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

Reauthorization Criteria

1. Documented diagnosis of Lambert-Eaton myasthenic syndrome

AND

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

AND

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

AND

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

LIMITATIONS

- Initial approval by the plan will be limited to 6 months. Reauthorizations will be provided in 12-month intervals.
- Members new to the plan stable on the requested medication should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. Firdapse (amifampridine) [prescribing information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; 2018 Nov.
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. Patwa HS, Chaudhry V, Katzberg H et al. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2012; 78(13):1009-15.
5. Portaro S, Brizzi T, Sinicropi S et al. Five years experience on 3,4-diaminopyridine phosphate in Lambert-Eaton syndrome: Case reports. Medicine (Baltimore). 2017; 96(38):e7839.
6. Ruzurgi (amifampridine) [prescribing information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc.; 2019 May.
7. Sanders DB, Juel VC, Harati Y et al. 3,4-diaminopyridine base effectively treats the weakness of Lambert-Eaton myasthenia. Muscle Nerve. 2018; 57(4):561-568.
8. 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 HISTORY

May 7, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 13, 2019: Changed title of Medical Necessity Guideline to "Amifampridine (Firdapse, Ruzguri)". Added Ruzguri to the Medical Necessity Guideline.
2. April 14, 2020: Effective July 1, 2020, removed age requirements for all amifampridine products. Modified reauthorization criteria and added the following Limitation: "Members new to the plan stable on the requested medication should be reviewed against Reauthorization Criteria."
3. January 12, 2021: No changes.

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.