Pharmacy Medical Necessity Guidelines: Dalfampridine

Effective: December 10, 2024

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617-673-0939	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS

Dalfampridine is a potassium channel blocker indicated to improve walking in adults with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

COVERAGE GUIDELINES

The plan may authorize coverage of dalfampridine for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of multiple sclerosis

AND

2. Documentation the patient has impaired ambulation as evaluated by an objective measure (e.g., Timed 25-Foot Walk, 12-item Multiple Sclerosis Walking Scale)

AND

3. Prescribed by or in consultation with a neurologist

AND

4. The Member is at least 18 years of age

LIMITATIONS

- The plan does not cover brand Ampyra. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives, Non-covered Pharmacy Products, or Pharmacy Products Without Specific Criteria.

CODES

None

REFERENCES

1. Ampyra (dalfampridine) [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc.; June 2022.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

- December 12, 2023: Added the requirement "Documentation the patient has impaired ambulation as evaluated by an objective measure" Updated wording of provider specialty requirements (eff 3/1/24).
- December 10, 2024: No changes (eff 12/10/24)

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. Provider Services