Pharmacy Medical Necessity Guidelines: Dalfampridine

Effective: July 1, 2020

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 (FDA)-APPROVED INDICATIONS

Ampyra (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.

MS is a chronic disease of the central nervous system characterized by inflammation, demyelination, and axonal degeneration. Most people are diagnosed between the ages of 20 and 50, although MS can occur in young children and significantly older adults.

It is believed that MS consists of both inflammatory and neurodegenerative components. Inflammation may be related to acute relapses, and it is believed that these acute attacks are associated with axon damage which leads to permanent neurologic dysfunction. The neurodegenerative component may contribute to the progressive disability that occurs over time.

The symptoms and severity of MS vary, and the course of the disease in an individual patient is often unpredictable. Common symptoms include sensory disturbances in the limbs leading to gait and balance problems, optic nerve dysfunction and vision loss, dysphagia, bladder or bowel dysfunction, sexual dysfunction, fatigue, emotional lability, and cognitive impairment.

Four categories of MS are recognized. Approximately 85% of patients are initially classified as having relapsing-remitting MS (RRMS) which is characterized by episodic relapses with partial or complete remissions. The majority of patients with RRMS will go on to develop secondary progressive MS (SPMS) which is characterized by an initial period of relapses and remissions, followed by a sudden progressive decrease in CNS function without periods of remission. Primary progressive MS (PPMS) is characterized by a steady decrease in CNS function from the onset without remissions or clear attacks. In contrast, patients with progressive-relapsing MS (PRMS) experience a steady decrease in CNS function from the onset and have clearly identifiable attacks. PPMS is the initial diagnosis in approximately 10% of patients while 5% of patients have PRMS.

Ampyra (dalfampridine) is a broad-spectrum potassium channel blocker FDA-approved to improve walking in patients with MS. The mechanism by which Ampyra (dalfampridine) exerts its therapeutic effect has not been fully elucidated. In animal studies, Ampyra (dalfampridine) has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels.

COVERAGE GUIDELINES

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

Initial Therapy

1. Documented diagnosis of multiple sclerosis

AND

2. The prescribing physician is a neurologist

AND

3. Documentation of timed 25-foot walk completed within 8 to 45 seconds

AND

4. Member receives concomitant treatment with a disease-modifying agent for multiple sclerosis

Reauthorization Criteria

1. Documented diagnosis of multiple sclerosis

AND

2. The prescribing physician is a neurologist

AND

3. Documentation the Member has experienced a therapeutic response as defined by at least one of the following:
    a. Stabilization or improvement in walking speed
    b. Stabilization or improvement in an objective measure of walking ability (e.g., 6MWT, EDDS)

LIMITATIONS

- Initial approval will be limited to 3 months.
- Members new to the plan stable on dalfampridine should be reviewed against Reauthorization Criteria.
- Coverage of dalfampridine tablets are limited to 60 units per 30 days.
- The plan does not cover the following medications on all Commercial and Medicaid formularies: 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

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APPROVAL HISTORY

July 13, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. September 14, 2010: Added requirement of completing timed 25 foot walk within 8 to 45 seconds
2. September 13, 2011: No changes.
3. September 11, 2012: No changes.
4. July 9, 2013: No changes.
5. July 8, 2014: Removed the following criteria: Documented ability to walk without the use of ambulatory aids
6. July 14, 2015: No changes.
7. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
8. July 12, 2016: No changes. Effective July 12, 2016 Medical Necessity Guideline applies to Tufts Health Together.
9. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
10. July 11, 2017: No changes.
11. July 10, 2018: No changes.
12. January 8, 2019: No changes.
13. April 14, 2020: Effective July 1, 2020, changed the name of the Medical Necessity Guideline to "Dalfampridine." Modified reauthorization criteria and added the following Limitation: "Members new to the plan stable on dalfampridine should be reviewed against Reauthorization Criteria." Added the following Limitation: The plan does not cover the following medications on all Commercial and Medicaid formularies: Ampyra. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives, Non-covered Pharmacy Products, or Pharmacy Products Without Specific Criteria.

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.