OVERVIEW

FDA-APPROVED INDICATIONS

Ampyra® (dalfampridine) is indicated as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Multiple sclerosis is a chronic disease of the central nervous system (CNS) characterized by inflammation, demyelination, and axonal degeneration. 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 MS 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. It is estimated that 50% of untreated patients will require an assistive walking device within 15 years of disease onset.

The mechanism by which dalfampridine exerts its therapeutic effect has not been fully elucidated. Dalfampridine is a broad spectrum potassium channel blocker. In animal studies, dalfampridine has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels.

A Risk Evaluation and Mitigation Strategy (REMS) program has been established to inform prescribers and patients regarding the risks associated Ampyra® (dalfampridine), in particular for drug-associated seizures. Elements of the REMS include provision of a medication guide with each filled prescription as well as a communication plan consisting of “Dear Healthcare Professional” letters. To facilitate the REMS program, a service hub will be used allowing for a single, initial point of contact for patients and prescribers. All patients will be triaged by the service hub to a specialty pharmacy within a limited network of authorized dispensers.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan - Network Health may authorize coverage of Ampyra® (dalfampridine) for Members when ALL of the following criteria are met:

1. Documented diagnosis of multiple sclerosis by a neurologist **AND**
2. Documentation of timed 25 foot walk completed within 8 to 45 seconds **AND**
3. Member receives concomitant treatment with a disease-modifying agent for multiple sclerosis.

LIMITATIONS

1. Initial authorization will be for a period of 12 weeks.
2. Additional authorization may be provided if there is documented improvement in walking speed from pre-treatment baseline by at least 25%.
3. Coverage of Ampyra® (dalfampridine) will be limited to 60 tablets per 30 days.

CODES

None
REFERENCES


APPROVAL HISTORY

- July 15, 201: Reviewed by the Pharmacy and Therapeutics Committee
- July 8, 2014: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.