Pharmacy Policy Bulletin

Title:	Dalfampridine (Ampyra®)
Policy #:	Rx.01.122

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria dalfampridine (Ampyra®) as provided under the member's prescription drug benefit.

Description:

Multiple sclerosis (MS) is the most common autoimmune, inflammatory, demyelinating disease affecting the central nervous system (CNS). An unknown stimulus causes the immune system to attack the myelin sheath that protects nerves, leading to symptoms such as weakness, numbness, vision loss, and gait disturbances. More than 2.3 million people are affected by MS worldwide.

Dalfampridine (Ampyra®) is indicated to improve walking in patients with MS.

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

Policy:

INITIAL CRITERIA: Dalfampridine (Ampyra®) is approved when ALL the following are met:

1. Diagnosis of multiple sclerosis; and
2. Member is 18 years of age or older; and
3. Member has difficulty walking; and
4. Prescribed by or in consultation with a neurologist.

Initial authorization duration: 6 months

CONTINUATION CRITERIA: Dalfampridine (Ampyra®) is re-approved when BOTH of the following are met:

1. Documentation of a 20% improvement in walking speed; and
2. Prescribed by or in consultation with a neurologist

Continuation authorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Ampyra® (dalfampridine) [package insert]. Ardsley, NY. Acorda Therapeutics, Inc. June 2022. Available from: https://ampyra.com/prescribing-information.pdf. Accessed April 18, 2023.

Olek, MJ. Mowry, E. Pathogenesis and epidemiology of multiple sclerosis. UpToDate. March 2023. Available at: https://www.uptodate.com/contents/pathogenesis-and-epidemiology-of-multiple-sclerosis. Accessed April 18, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Ampyra®	Dalfampridine

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	14.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	March 16, 2024