

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 has difficulty walking; AND
3. Prescribed by or in consultation with a neurologist.

Initial authorization: 6 months

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

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

Continuation: 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. February 2021. Available from: <https://ampyra.com/prescribing-information.pdf>. Accessed March 31, 2021.

Olek, MJ. Mowry, E. Pathogenesis and epidemiology of multiple sclerosis. UpToDate. June 2018. Available at: <https://www.uptodate.com/contents/pathogenesis-and-epidemiology-of-multiple-sclerosis>. Accessed March 31, 2021.

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:	12.00
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 01, 2021
Next Required Review Date:	March 18, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

