

# **Pharmacy Drug Policy & Procedure**

Policy Name:	Dalfampridine	Policy #:	1854P	
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# **Purpose of the Policy**

The purpose of this policy is to establish the criteria for coverage of dalfampridine (generic Ampyra).

## **Statement of the Policy**

Health Alliance Medical Plans will approve the use of dalfampridine (generic Ampyra) under the specialty pharmacy benefit when the criteria below have been met.

### Criteria

## 1. Coverage Criteria

- 1.1 Diagnosis of multiple sclerosis (MS)
  Prescribed by a neurologist (nervous system doctor)
- 1.2 Patient must be 18 years of age or older
- 1.3 Ambulatory (able to walk)
- 1.4 No history of seizures
- 1.5 25-foot walk Test Completion
  - Initial coverage: Member has completed two (2) in office 25-foot timed walk tests (with no more than five (5) minute break between tests) AND the average time is submitted as baseline
  - Continued coverage: Member has achieved a 20% decrease in time to walk 25 feet from baseline while on treatment with Ampyra
  - All walk tests must be conducted in office by ordering prescriber
- 1.6 Documentation that patients with relapsing-remitting multiple sclerosis are on concurrent therapy with a disease modifying agent (such as Aubagio)

#### 2. Authorization Criteria

- 2.1 Initial approval: 12 months
- 2.2 Subsequent approvals: 12 months approval based on therapeutic response defined as at least a 20% decrease in the average 25 foot walk test time compared to baseline

#### 3. Discontinuation Criteria

- 3.1 Experience a seizure, OR
- 3.2 Kidney impairment with a creatinine clearance less than (<) 80mL/min, OR
- 3.3 Wheelchair bound

CPT Codes		
<b>HCPCS Codes</b>		

# References

- 1. Ampyra (dalfampridine) [prescribing information]. Pearl River, NY: Acorda Therapeutics Inc; June 2022.
- 2. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2019 Jan 8;92(2):112.
- 3. Goodman AD, Brown TR, Edwards KR, et al. A Phase 3 Trial of Extended Release Oral Dalfampridine in Multiple Sclerosis. Ann Neurol. 2010;68(4):494-502
- 4. Raffel JB, Malik O, Nicholas RS. Assessing dalfampridine efficacy in the physician's office. Mult Scler 2014; 20:24.

Created Date: 10/01/14 Effective Date: 10/01/14 Posted to Website: 01/01/22 Revision Date: 08/07/24

#### **DISCLAIMER**

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.