MEDICAL MUTUAL®

Drug Policy

Policy:	Ampyra ® (dalfampridine)	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023

OVERVIEW

Dalfampridine is a potassium channel blocker that is indicated to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed.

POLICY STATEMENT

This policy involves the use of dalfampridine. Prior authorization is recommended for pharmacy benefit coverage of dalfampridine. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with dalfampridine as well as the monitoring required for adverse events and long-term efficacy, initial approval requires dalfampidine be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of dalfampridine is recommended in those who meet the following criteria:

FDA Approved Indications

1. **Multiple Sclerosis (MS).** The patient must meet the following criteria (A, B, C, D, E, F, G, and H):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is ambulatory; AND
   - **C)** Dalfampridine is being used to improve or maintain mobility; AND
   - **D)** Patient has impaired ambulation as evaluated by an objective measure; AND
     Note: Examples of objective measures of ambulation include the Timed 25-Foot Walk and Multiple Sclerosis Walking Scale-12.
   - **E)** Medication is being prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
   - **F)** The patient meets one of the following criteria (i or ii):

i. Patient has tried generic dalfampridine **[documentation required]**; AND

ii. Patient cannot continue to use generic dalfampridine due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**.

2. **Patient Currently Receiving Dalfampridine (re-authorization).** Approve if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is ambulatory; AND
   - **C)** Dalfampridine is being used to improve or maintain mobility; AND
   - **D)** Patient has impaired ambulation as evaluated by an objective measure; AND
     Note: Examples of objective measures of ambulation include the Timed 25-Foot Walk and Multiple Sclerosis Walking Scale-12.
   - **E)** Dalfampridine is being prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
   - **F)** According to the prescriber the patient has experienced an improvement or maintenance in walking speed or other objective measures related to ambulation.
     Note: Examples of objective measures of ambulation include the Timed 25-Foot Walk and Multiple Sclerosis Walking Scale-12.
   - **G)** The patient meets one of the following criteria (i or ii):
     - **i.** Patient has tried generic dalfampridine **[documentation required]**; AND
     - **ii.** Patient cannot continue to use generic dalfampridine due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 4 months (120 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Dalfampridine has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ampyra® extended-release tablets [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc.; September 2017.

2. Goodman AD, Brown TR, Krupp LB, et al, on behalf of the Fampridine MS-F203 Investigators. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. *Lancet*. 2009;373:732-738.
3. Goodman AD, Brown TR, Edwards KR, et al, on behalf of the MSF204 investigators. A phase 3 trial of extended-release oral dalfampridine in multiple sclerosis. *Ann Neurol*. 2010;68:494-502.
4. Dalfampridine. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: http://www.online.lexi.com. Last updated 17 January 2020. Accessed on 15 February 2020.

Other References Utilized

- Chwieduk CM, Keating GM. Dalfampridine extended-release in multiple sclerosis. *CNS Drugs*. 2010;24(10):883-891.
- Hobart J, Blight AR, Goodman A, et al. Timed 25-foot walk: direct evidence that improving 20% of greater is clinically meaningful in MS. *Neurology*. 2013;80(16):1509-1517.