

PRIOR AUTHORIZATION POLICY

POLICY: Multiple Sclerosis – Dalfampridine Prior Authorization Policy

- Ampyra® (dalfampridine extended-release tablets – Acorda, generic)

REVIEW DATE: 10/09/2024

OVERVIEW

Dalfampridine, a potassium channel blocker, is indicated to improve walking in adults with **multiple sclerosis**.¹ This was demonstrated by an increase in walking speed.

Safety

Dalfampridine is contraindicated in patients with a history of seizures; moderate or severe renal impairment (estimated creatinine clearance ≤ 50 mL/min); and in those with a of hypersensitivity to dalfampridine or 4-aminopyridine.¹

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of dalfampridine. All approvals are provided for the duration noted below. 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, approval requires dalfampridine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

- 1. Multiple Sclerosis (MS).** Approve for the duration noted below if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 4 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
 - i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient is ambulatory; AND
 - iii.** Dalfampridine is being used to improve or maintain mobility; AND
 - iv.** 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.
 - v.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
 - B) Patient Currently Receiving Dalfampridine.** Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
 - i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient is ambulatory; AND
 - iii.** Dalfampridine is being used to improve or maintain mobility; AND

- iv. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
- v. 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of dalfampridine is not recommended in the following situations:

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]. Pearl River, NY: Acorda; June 2022.