Drug Coverage Policy

Effective Date……11/15/2025
Coverage Policy Number……IP0024
Policy Title……Dalfampridine

Multiple Sclerosis – Dalfampridine

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

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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/minute); and in those with a history of hypersensitivity to dalfampridine or 4-aminopyridine.[1]

Coverage Policy

Policy Statement
Prior Authorization is required for 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.

Dalfampridine is considered medically necessary when the following are met:

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, v and vi):
     - **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 test 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; AND
     - **vi.** Preferred product criteria is met for the product(s) as listed in the below table(s); OR
   - **B)** Patient Currently Receiving Dalfampridine. Approve for 1 year of 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.

Employer Plans:

Product	Criteria
Ampyra (dalfampridine)	Patient has tried **dalfampridine extended-release tablet** (the bioequivalent generic product) [requires prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives]

Product	Criteria
	between the brand and the bioequivalent generic product, which would result in a significant allergy or serious adverse reaction.

Individual and Family Plans:

Product	Criteria
Ampyra (dalfampridine)	Patient has tried **dalfampridine extended-release tablet** (the bioequivalent generic product) [requires prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which would result in a significant allergy or serious adverse reaction.

Conditions Not Covered

Dalfampridine for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Ampyra® extended-release tablets [prescribing information]. Pearl River, NY: Acorda; June 2022.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Policy title updated from "Dalfampridine" to "Multiple Sclerosis – Dalfampridine". **Added** a policy statement. **Updated** the dalfampridine use to improve or maintain mobility requirement. **Updated** the impaired ambulation requirement. **Added** criteria for a patient currently receiving dalfampridine. **Updated** the preferred product requirements. **Updated** the Conditions Not Covered statement.	11/15/2025

The policy effective date is in force until updated or retired.