Effective Date **2/15/2024**
Next Review Date… **2/15/2025**
Coverage Policy Number **IP0024**

Dalfampridine

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Related Coverage Resources

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. 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

This policy supports medical necessity review for dalfampridine (dalfampridine extended-release tablet and Ampyra®).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Dalfampridine (Ampyra and dalfampridine extended-release tablet) is considered medically necessary when the individual meets ALL of the following criteria are met:

A. 18 years of age or older
B. Individual is ambulatory

C. Dalfampridine (Ampyra or dalfampridine extended-release tablet) is being used to improve or maintain ambulation in an individual with multiple sclerosis
D. Prior to treatment with dalfampridine (Ampyra or dalfampridine extended-release tablet), the individual has been assessed for impaired ambulation using an objective measure (for example, Timed 25-foot Walk test, Multiple Sclerosis Walking Scale-12 or another objective measure of gait)
E. Medication is prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of multiple sclerosis
F. Preferred products are required, refer to below table:

Employer Group Plans Preferred Alternative(s):

Product	Criteria
Ampyra (dalfampridine)	Documented trial of **dalfampridine extended-release tablet** (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

Individual and Family Plan Preferred Alternative(s):

Product	Criteria
Ampyra (dalfampridine)	Documented trial of **dalfampridine extended-release tablet** (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of dalfampridine (Ampyra or dalfampridine extended-release tablet) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response (for example, an increase in walking speed or a maintained level of ambulation).

Authorization Duration

Initial approval duration: up to 6 months.
Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
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 history of hypersensitivity to dalfampridine or 4-aminopyridine.[1]

References

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