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5.60.002

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	June 19, 2013
Subject:	Ampyra	**Page:**	1 of 5

Last Review Date: December 13, 2024

Ampyra

Description

Ampyra* (dalfampridine)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication

Background
Ampyra (dalfampridine) is indicated for improving walking ability in patients with MS (1). Ampyra is a broad-spectrum potassium channel blocker that improves conduction of action potentials in demyelinated axons. Myelin destruction is considered a pathologic hallmark of multiple sclerosis. Demyelination exposes potassium channels, impairing the conduction and generation of action potential through the neuronal axons. As this is correlated with the appearance of clinically significant symptoms, restored conduction should enhance the quality of life for a MS patient (2-3).

Regulatory Status
FDA-approved indication: Ampyra (dalfampridine) is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS) (1).

Ampyra can cause seizures. The majority of seizures occurred at the recommended dose and in patients without a history of seizures, and generally within days to weeks of starting therapy. Ampyra should be discontinued and not restarted in patients who experience a seizure while on treatment. Ampyra is contraindicated in patients with a history of seizures (1).

Ampyra is eliminated through the kidneys primarily as unchanged drug. Because patients with moderate to severe renal impairment (CrCl ≤50mL/min) would require a dose lower than 10 mg

twice daily and no strength smaller than 10 mg is available, Ampyra is contraindicated in these patients (1).

In patients with mild renal impairment (CrCl 51–80 mL/min), Ampyra plasma levels may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures. As mild renal impairment is common after age 50, estimating CrCl is particularly important in these patients. The potential benefits of Ampyra should be carefully considered against the risk of seizures in these patients (1).

Ampyra should not be taken with other forms of 4-aminopyridine (4-AP, fampridine) since the active ingredient is the same. Patients should discontinue use of any product containing 4-aminopyridine prior to initiating treatment with Ampyra in order to reduce the potential for dose-related adverse reactions (1).

Safety and effectiveness of Ampyra in patients younger than 18 years of age have not been established (1).

Related policies
Acthar Gel, Aubagio, Briumvi, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, MS Injectables, Ocrevus, Ponvory, Tecfidera, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ampyra may be considered **medically necessary** if the conditions indicated below are met.

Ampyra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Multiple Sclerosis with sustained walking impairment

AND NONE of the following:
   a. History of seizure
   b. Moderate or severe renal impairment (CrCl≤50 mL/min)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Multiple Sclerosis

AND ONE of the following:
   a. Improvement in walking speed since initiation of Ampyra
   b. Improvement in an objective measure of walking ability since starting Ampyra

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 180 tablets per 90 days

Duration 3 months

Prior – Approval *Renewal* Limits

Quantity 180 tablets per 90 days

Duration 12 months

Rationale

Summary
Ampyra (dalfampridine) is a broad-spectrum potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS). The use of Ampyra in patients with a history of seizure and in patients with moderate or severe renal impairment is contraindicated. Safety and effectiveness in patients younger than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Ampyra while maintaining optimal therapeutic outcomes.

References

1. Ampyra [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; June 2022.
2. Korenke AR, Rivey MP, Allington DR. Sustained-release fampridine for symptomatic treatment of multiple sclerosis. *Ann Pharmacother*. 2008; 42:458-465.
3. Feret B. Fampridine-SR: a potassium-channel blocker for the improvement of walking ability in patients with MS. *Formulary*. 2009; 44:293-299.

Policy History

Date	Action
June 2013	Addition to PA
September 2013	Annual editorial review by PMPC
December 2014	Annual editorial review by PMPC
March 2015	Annual editorial review and reference update
June 2016	Annual review and reference update Policy code changed from 5.06.11 to 5.60.02
June 2017	Annual review
November 2018	Annual editorial review and reference update
June 2019	Annual review
September 2019	Annual review
December 2019	Annual review. Addition of requirement to trial preferred product
March 2020	Annual review
September 2020	Annual review and reference update
December 2020	Annual review. Removed requirement to trial preferred product. Added notation that Ampyra brand name requires MFE
March 2021	Annual review
June 2021	Annual review and reference update
March 2022	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.60.002
March 2023	Annual review and reference update

June 2023	Annual review
December 2023	Annual review
March 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.