BlueCross BlueShield
Federal Employee Program

AMPYRA* (dalfampridine)

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

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.