Clinical Policy: Dalfampridine (Ampyra)

Reference Number: PA.CP.PHAR.248
Effective Date: 01/18
Last Review Date: 04/19

Revision Log

Description
Dalfampridine (Ampyra®) is a potassium channel blocker.

FDA Approved Indication(s)
Ampyra is indicated to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Ampyra is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Member has sustained walking impairment but is able to walk with or without assistance;
5. Dose does not exceed 20 mg (2 tablets) per day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Multiple Sclerosis (must meet all):

1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 20 mg (2 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53**.**

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CrCl: creatinine clearance
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): history of seizure; moderate or severe renal impairment (CrCl ≤ 50 mL/min); history of hypersensitivity to Ampyra or 4-aminopyridine
- Boxed warning(s): none reported

Appendix D: General Information
- Use of doses above 10 mg twice daily may increase the risk of seizures.
- Patients with mild renal impairment (CrCl 51-80 mL/min) may exhibit Ampyra levels that approach those attained at higher doses and that have been associated with a higher risk of seizures. Ampyra should be used with caution in this patient population, and CrCl should be estimated or known prior to initiating Ampyra therapy.
- CrCl can be estimated using the Cockcroft-Gault formula: CrCl = [(140-age) x (weight in kg) x (0.85 if female)] / (72 x Cr).

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MS	10 mg PO BID (approximately 12 hours apart)	20 mg/day

V. Product Availability

Tablet: 10 mg

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed history of seizure; references reviewed and updated.	01.05.18	
2Q 2019 annual review: references reviewed and updated.	04.17.19	

References

1. Ampyra Prescribing Information. Ardsley NY: Acorda Therapeutics, Inc; September 2017. Available at http://www.ampyra.com. Accessed January 7, 2019.

2. Samkoff LM, Goodman AD. Symptomatic management in multiple sclerosis. Neurol Clin. 2011; 29: 449-463.