Clinical Policy: Dalfampridine (Ampyra)

Reference Number: ERX.SPA.111
Effective Date: 10.01.16
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Ampyra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of 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. If request is for brand Ampyra, member has experienced clinically significant adverse effects to generic dalfampridine or has contraindication(s) to its excipients;
6. Dose does not exceed 20 mg (2 tablets) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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. There is no evidence of additional benefit with doses greater than 10 mg twice daily.
- 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).

V. Dosage and Administration

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

VI. Product Availability

Tablet: 10 mg

VII. References

1. Ampyra Prescribing Information. Ardsley NY: Acorda Therapeutics, Inc.; December 2019. Available at http://www.ampyra.com. Accessed January 27, 2020.
2. Samkoff LM, Goodman AD. Symptomatic management in multiple sclerosis. Neurol Clin. 2011; 29: 449-463.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Removed all safety criteria. Removed requirement for 25-foot walk documentation, removed re-authorization requirement for documented adherence, modified efficacy criteria from "Has experienced improvement in an objective measure of walking ability since initiation of Ampyra" to "Responding positively to therapy". Modified approval duration to 6 months for initial and 12 months for re-auth.	08.16	09.16
Converted to new template.	06.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added age requirement as safety and efficacy have not been established in pediatric populations. Removed MRI requirement as it is a non-specific diagnostic test (plus, specialist involvement in care is required). Added contraindication of severe renal impairment as the resulting adverse reaction (increased seizure risk) can result in hospitalization or death.		
2Q 2018 annual review: No significant changes. References reviewed and updated.	01.05.18	05.18
2Q 2019 annual review: no significant changes; added re-direction to generic dalfampridine for requests for brand Ampyra since the generic is the preferred product on formulary; removed renal impairment contraindication per safety guidance (the resulting adverse reaction is not predictable); references reviewed and updated.	01.07.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	01.27.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.