Clinical Policy: Dalfampridine (Ampyra)

Reference Number: CP.PHAR.248
Effective Date: 08.01.16
Last Review Date: 05.20
Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation® 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:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 CP.PHAR.18 MS Treatments. Criteria: removed monotherapy; 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". Changed renewal approval duration to 12 months.	07.16	08.16
Added age requirement. Removed MRI requirement. Removed hypersensitivity contraindication. Removed reasons to discontinue.	07.17	08.17
2Q 2018 annual review: no significant change from previously approved corporate policy; policies combined for Commercial, Medicaid and HIM; Medicaid: removed history of seizure; HIM: removed MRI requirement; added age restriction; Commercial: added requirement that member must have walking impairment; added age; references reviewed and updated.	01.05.18	05.18
2Q 2019 annual review: no significant changes; removed PPMS from diagnoses not covered since the FDA approved indication does not limit use to RRMS or SPMS; references reviewed and updated.	01.07.19	05.19
2Q 2020 annual review: no significant changes; added re-direction to generic dalfampridine per SDC; 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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.