Clinical Policy: Dalfampridine (Ampyra)

Reference Number: CP.PHAR.248
Effective Date: 08/16
Last Review Date: 08/17

Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for dalfampridine (Ampyra®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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. Sustained walking impairment but member is able to walk with or without assistance;
5. At the time of request, member does not have any of the following contraindications:
   a. History of seizure;
   b. Moderate or severe renal impairment (creatinine clearance ≤ 50 mL/min);
6. Dose does not exceed 20 mg/day (2 tablets/day).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy (e.g., improvement in walking ability);
3. If request is for a dose increase, new dose does not exceed 20 mg/day (2 tablets/day).

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background
Description/Mechanism of Action:

Ampyra is a broad spectrum potassium channel blocker. The mechanism by which it exerts its therapeutic effect has not been fully elucidated.

Formulations:
Ampyra extended release tablets, 10 mg are film-coated, white to off-white, biconvex, oval shaped, non-scored tablets with flat edge. The tablets are identified by a debossed code "A10" on one side and are available in bottles of 60.

FDA Approved Indication(s):
Ampyra is a potassium channel blocker/oral tablet indicated as:
- Treatment to improve walking in patients with MS.

Appendices
Appendix A: Abbreviation Key
FDA: Food and Drug Administration
MS: multiple sclerosis

Reviews, Revisions, and Approvals	Date	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

References
1. Ampyra Prescribing Information. Ardsley NY: Acorda Therapeutics, Inc; October 2016. Available at http://www.ampyra.com. Accessed June 14, 2017.
2. Olek MJ. Symptom management of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed June 14, 2017.
3. Olek MJ. Diagnosis of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed June 13, 2017.

"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.

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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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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