Clinical Policy: Dalfampridine (Ampyra)

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

Revision Log

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

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. Sustained walking impairment but member is able to walk with or without assistance;
5. Dose does not exceed 20 mg/day (2 tablets/day).

Approval duration: 6 months

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

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 (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 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.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.

Appendices

Appendix A: Abbreviation Key

FDA: Food and Drug Administration
MS: multiple sclerosis

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

References

1. Ampyra Prescribing Information. Ardsley NY: Acorda Therapeutics, Inc; October 2016. Available at http://www.ampyra.com. Accessed January 5, 2018.
   Olek MJ. Symptom management of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed January 5, 2018.