Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Ampyra (dalfampridine)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Ampyra (dalfampridine).

Ampyra (dalfampridine) is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS) as demonstrated by increase in walking speed.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Ampyra (dalfampridine), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by one of the following: o Neurologist
- Physical Medicine and Rehabilitation physician in consultation with the member's treating Neurologist
- Must have a diagnosis of multiple sclerosis
- Must have chart documentation of member's baseline motor disability/dysfunction
- Must be age 18 years or older
- Must not be on concomitant therapy with any other forms of 4-aminopyridine
- Must not have a history of seizure
- Must not have moderate or severe renal impairment (CrCl ≤ 50 mL/min)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Ampyra™ [package insert]. Hawthorne, NY: Acorda Therapeutics, Inc.: January 2010
2. Goodman AD, Brown TD, Krupp LB et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. *Lancet* 2009;373:732-38
3. Goodman AD, Brown TR, Cohen JA et al. Fampridine MS-F202 Study Group. Dose comparison trial of sustained-release fampridine in multiple sclerosis. *Neurology* 2008;71:1134-1141

4. Kachuck NJ. Sustained release oral fampridine in the treatment of multiple sclerosis. *Expert Opin Pharmacother* 2009;10(12):2025-2035

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*
Criteria update	*07/16*