dalfampridine ER (Ampyra®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO103

Description

Dalfampridine ER (Ampyra) is an orally administered broad-spectrum potassium channel blocker with an unknown mechanism of action for its therapeutic effect.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
Dalfampridine ER (Ampyra)	10 mg tablets	Improve walking in patients with multiple sclerosis	60 tablets/30 days

Initial Evaluation

I. Dalfampridine ER (Ampyra) may be considered medically necessary when the following criteria below are met:
   A. Member must be 18 years of age or older; **AND**
   B. Must be prescribed by or in consultation with a neurologist; **AND**
   C. A diagnosis of **multiple sclerosis** when the following are met:
      1. Member does not have a history of seizures; **AND**
      2. Member has a CrCl >50 mL/min; **AND**
      3. Member must be able to ambulate; **AND**
      4. Member must currently be receiving a disease modifying therapy for multiple sclerosis (i.e. glatiramer acetate, dimethyl fumarate, interferon beta-1a, etc.); **AND**
      5. If request is for brand Ampyra, documentation of treatment with generic dalfampridine ER has been ineffective, contraindicated, or not tolerated.

II. Dalfampridine ER (Ampyra) is considered investigational when used for all other conditions, including but not limited to:
   A. Acute spinal cord injury
   B. Disorder of neuromuscular transmission
   C. Alzheimer's disease, dementia
   D. Botulism

E. Reversal of neuromuscular blockade
F. Toxicity of calcium channel blockers
G. Non-ambulating members with multiple sclerosis

Renewal Evaluation

I. Member has demonstrated disease stability or lack of disease progression (e.g improvement in walking distance).

Supporting Evidence

I. Dalfampridine ER (Ampyra) was studied in two randomized controlled trials that evaluated improvement in the timed 25-foot walk using percentage of timed walk responders as the primary outcome. Patients included in the clinical trials were required to be able to ambulate. Dalfampridine ER (Ampyra) had a significantly greater number of responders compared to placebo in both trials. Trial one had 42.9% vs 9.3% responders ($p<0.0001$) for dalfampridine ER (Ampyra) and placebo respectively. Trial two had 35% vs 8% responders ($p<0.0001$) for dalfampridine ER (Ampyra) and placebo respectively.
II. Use of dalfampridine ER (Ampyra) is contraindicated in a patient with a prior history of seizure. Seizures have been reported in patients with no history of seizure. Permanent discontinuation is advised if seizures occur.
III. Use of dalfampridine ER (Ampyra) is contraindicated in patients with a CrCl less than 50 mL/min. Minor renal impairment (CrCl 51 to 80 mL/min) may increase risk of seizures.

Investigational or Not Medically Necessary Uses

I. Dalfampridine ER (Ampyra) has not been adequately studied for the following conditions and does not have established safety and efficacy in these populations:
   A. Acute spinal cord injury
   B. Disorder of neuromuscular transmission
   C. Alzheimer's disease, dementia
   D. Botulism
   E. Reversal of neuromuscular blockade
   F. Toxicity of calcium channel blockers
II. Dalfampridine ER (Ampyra) was only studied in patients able to ambulate and is not indicated for non-ambulating members with multiple sclerosis

References

1. Dalfampridine ER [Prescribing Information]. Basking Ridge, NJ: Micro Labs USA, Inc. March 2019.
2. UpToDate, Inc. Symptom management of multiple sclerosis in adults. UpToDate [database online]. Waltham, MA. Updated 09/24/2019. Available at: http://www.uptodate.com/home/index.html. [Accessed 10/08/2019].
3. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet. 2009;373(9665):732-8.
4. Goodman AD, Brown TR, Edwards KR, et al. A phase 3 trial of extended release oral dalfampridine in multiple sclerosis. Ann Neurol. 2010;68(4):494-502.

Policy Implementation/Update:

Date Created	October 2011
Date Effective	October 2011
Last Updated	October 2019
Last Reviewed	05/2013, 01/2016, 11/2018, 10/2019

Action and Summary of Changes	Date
Transitioned criteria to policy	10/2019