

## Commercial/Healthcare Exchange PA Criteria

Effective: July 27, 2016

**Prior Authorization:** Dalfampridine

**Products Affected:** Ampyra extended release oral tablets; dalfampridine extended release oral tablets

**Medication Description:**

Dalfampridine is a broad spectrum potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS). The mechanism by which dalfampridine exerts its therapeutic effect has not been fully elucidated. In animal studies, dalfampridine has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels. In clinical trials, improvement in walking was demonstrated by an increase in walking speed.

**Covered Uses:** Improve walking ability in patients with multiple sclerosis (MS)

**Exclusion Criteria:**

1. History of seizure
2. Moderate or severe renal impairment ( $CrCl \leq 50$  mL/min)

**Required Medical Information:**

1. Documented diagnosis of multiple sclerosis
2. Prescriber confirmation of difficulty walking

**Age Restrictions:** 18 years of age and older

**Prescriber Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:**

- A. Patient has a documented diagnosis of multiple sclerosis; AND
- B. Patient is receiving concomitant treatment with a disease-modifying agent for multiple sclerosis; AND
- C. Prescriber has confirmed the patient has difficulty walking (with or without assistance); AND
- D. Patient has the ability to walk 25 feet. Documentation of a baseline timed 25-foot walking speed is required; AND
- E. Patient's baseline 25-foot walking speed is equal to, or the equivalent of, 8-45 seconds

**References:**

1. Ampyra [package insert]. Acorda Therapeutics, Inc. Ardsley, NY. January 2014.
2. Goodman AD, Bethoux F, Brown TR, et al. Long-term safety and efficacy of dalfampridine for walking impairment in patients with multiple sclerosis: Results of open-label extensions of two Phase 3 clinical trials. *Mult Scler.* 2015 Jan 12.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/2/16
2	Update	<p>Moved to updated template</p> <p>CCI Revision History: 12/10, 1/16</p> <p>Removed from Other Criteria: EDS score requirement, patent has not had an exacerbation in the last 60 days</p> <p>Increased coverage duration to 12 months</p>	All	2/7/2020