



## Prior Authorization Approval Criteria

### *Ampyra (dalfampridine)*

<b>Generic name:</b>	dalfampridine
<b>Brand name:</b>	Ampyra
<b>Medication class:</b>	Potassium Channel blocker
<b>FDA-approved uses:</b>	Improvement of walking ability in multiple sclerosis (MS) patients
<b>Available dosage forms:</b>	10mg tablets
<b>Usual dose:</b>	10mg twice a day every 12 hours. Doses greater than 10mg twice daily did not show any greater benefit and adverse events, including seizures, were more frequent
<b>Approximate monthly cost:</b> (based on AWP 2010)	\$1,267.20/month
<b>Duration of therapy:</b>	indefinite

#### **Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be prescribed by a neurologist
- Must have a confirmed diagnosis of multiple sclerosis.
- Must have a walking impairment:
  - Must be able to complete the 25 foot walk with in 8-45 seconds.
  - Or
  - If 25 foot walk is less than 8 seconds than the Expanded Disability Status Scale (EDSS) must be between 4.5-6.5.
- Patient does not have a history of seizures.
- Patient must have normal renal function ( $\text{CrCl} \geq 50\text{mL/min}$ ) (must provide recent Scr and Bun levels.)
- Must be 18-70 years of age. (unknown adverse effects with patients older than 70 due to decrease renal function and increase risk of seizures)
- Quantity limit of 60/month.
- Currently on disease modifying therapy for MS

#### **Criteria for continuation of therapy:**

- Improvement on 25 foot time walk with faster speeds within 4 weeks in order to continue Ampyra. (at least 20% improvement in timed walking speeds)
- After six months of therapy, documentation of patient's improvement in walking must be submitted for continuation of treatment.

#### **Caution:**

- Ampyra causes seizures in a dose dependent fashion.

#### **Contraindication:**

- History of seizure disorders
- Patients with moderate to severe renal impairment; the risk of seizures in patients with

mild renal impairment is unknown, but plasma levels of Ampyra in these patients may approach those seen at a dose of 15mg twice daily, a dose that may be associated with an increased risk of seizures.

**Not approved if:**

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of Ampyra

**Special considerations:**

- Ampyra causes seizures in a dose dependent fashion, and that they must discontinue use of Ampyra if they experience a seizure.
- Improve walking in MS patients demonstrated by an increase in walking speed.
- No disease modification, just improvement in walking speed.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/09/10