## Ampyra
*(dalfampridine extended-release tablets)*

### Prior Authorization Criteria

**Drugs Addressed in the Policy**
- Ampyra (dalfampridine)

**FDA-Approved Indication(s)**
- For improved walking in patients with multiple sclerosis

**Background**
- Dalfampridine is a broad spectrum potassium channel blocker. The mechanism of dalfampridine's therapeutic effect has not been fully elucidated. In animals, inhibition of potassium channels increased action potential conduction in demyelinated axons.
- Dalfampridine is a potassium channel blocker indicated to improve walking ability in patients with MS. The primary efficacy outcome used in the clinical trials that evaluated the safety and efficacy of dalfampridine was a responder analysis using the Timed 25 Foot Walk test (T25W).

**Limitations of Coverage**
- Dalfampridine should not be prescribed for patients with a history of seizure disorder or with moderate to severe renal impairment (CrCl < 50mL/min).

**Approval Criteria**

I. **Initiation**
   When a benefit, initiation of dalfampridine may be approved when the member meets all the following criteria:
   A. The member has a documented diagnosis of multiple sclerosis (ICD-9 340, ICD-10 G35).
   B. The prescribed dose of dalfampridine does not exceed 20mg per day.
   C. The member is ambulatory and has walking impairment related to MS as evidenced by one of the following (1. or 2.):
      1. The member has a documented EDSS score between 2.5 and 7.
      2. The member has a documented timed 25-foot walk test (T25W) between 8 and 45 seconds.
   D. The prescriber has documented a baseline timed 25-foot walk test (T25W).

II. **Continuation**
   When a benefit, continuation of dalfampridine may be approved when the member meets all the following criteria:
   A. The member has a documented diagnosis of multiple sclerosis (ICD-9 340, ICD-10 G35).
   B. The prescribed dose of dalfampridine does not exceed 20mg per day.
C. The member was ambulatory and had walking impairment related to MS at baseline as evidenced by one of the following (1. or 2.):
   1. The member has a documented EDSS score between 2.5 and 7.
   2. The member has a documented timed 25-foot walk test (T25W) between 8 and 45 seconds.
D. The prescriber has documented a baseline timed 25-foot walk test (T25W).
E. The member has a documented 20% improvement from baseline in timed 25-foot walk test (T25W).

- Use of dalfampridine in disease states outside of its FDA-approved indication should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.
- For members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Duration of Authorization
I. **Initiation**: If approved, a 3 month authorization will be granted.
II. **Continuation**: If approved, a 12 month authorization will be granted.

References: