

***Title: dalfampridine (Ampyra)***

<b>Origination:</b> 08/23/10	<b>Revised:</b> 05/25/11	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Medication Summary***

- The mechanism by which dalfampridine exerts its therapeutic effect has not been fully elucidated. Dalfampridine is a broad spectrum potassium channel blocker. In animal studies, dalfampridine has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels.
- Dalfampridine is indicated as a treatment to improve walking in patients with multiple sclerosis.
- Dalfampridine is administered as 10 mg by mouth twice daily (every 12 hours) with or without food (maximum daily dose = 20 mg).

***Reference Statement***

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Eligibility Criteria***

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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**Procedure:**

- 1.0 Request for therapy with Ampyra for **multiple sclerosis (MS)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
  - 1.1 Member is at least 18 years of age;
  - 1.2 Diagnosis of multiple sclerosis (MS);
  - 1.3 Member has **no** history of seizures/evidence of epileptiform activity on EEG;
  - 1.4 Member does **not** have moderate to severe renal impairment ( $\text{CrCl} \leq 50 \text{ ml/min}$ );
  - 1.5 Member is able to walk 25 feet in 8-45 seconds;
  - 1.6 If all criteria are met, therapy carries a lifetime approval.

**Reference:**

1. Ampyra (dalfampridine) Prescribing Information. Acorda Therapeutics Inc. Hawthorn, NY. January 2010.

**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.