Ampyra (dalfampridine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial request: 12 weeks Maintenance therapy request: 12 months

Medications	Quantity Limit
Ampyra (dalfampridine)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Ampyra (dalfampridine) may be approved if the following criteria are met:

I. Individual has a diagnosis of Multiple Sclerosis (MS); **AND**
II. Individual has been objectively assessed for function impairment related to ambulation.

Maintenance therapy requests for Ampyra (dalfampridine) may be approved if the following criteria are met:

I. Individual has achieved and sustained clinically significant improvement in ambulation-related functional status.

Requests for **brand** Ampyra must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial of one chemically equivalent generic dalfampridine agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
    A. Generic dalfampridine had inadequate response; **OR**
    B. Generic dalfampridine caused adverse outcome; **OR**
    C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Ampyra (dalfampridine) may not be approved for the following:

I. Individual has a history of seizures; **OR**
II. Individual has moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/min).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 7, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018; 90: 777-788. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: July 7, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.