HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Dalfampridine (generic for Ampyra)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ampyra is a potassium channel blocker indicated to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed in clinical trials. Ampyra was approved by the FDA in 2010 and is supplied as extended-release oral tablets. It is a symptomatic treatment and does not alter the overall progression of disease, thus it is typically used as an add on to disease modifying treatment.

Dalfampridine will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of MS (any type); AND
4. Member is ambulatory (with or without assistive device) with impaired walking ability; AND
5. Member has a baseline timed 25-foot walk (T25FW) between 8 and 45 seconds; AND
6. Member does NOT have a history of seizures; AND
7. Member does NOT have moderate or severe renal impairment (CrCl 50 mL/min or less).
8. **Dosage allowed/Quantity limit:** 10 mg every 12 hours. (QL: 60 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must include documentation of increased walking speed compared to baseline (e.g., improved T25FW).

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers dalfampridine not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/18/2017	New policy for Ampyra created. Not covered diagnosis added.
05/16/2019	Policy modified to Dalfampridine (generic for Ampyra). Mayzent and Mavenclad added to the list of disease modifying agents; Zinbryta was removed due to market recall.
07/26/2022	Transferred to new template. Updated and added references. Added diagnosis of MS. Added impaired walking ability. Added contraindications. Removed requirement to be on a concomitant drug. Shortened initial approval duration from 6 mo to 3 mo. Slight modification to renewal criteria wording.
04/28/2025	Annual review; no updates.

References:

1. Ampyra [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; 2022.
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3. 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;21(10):1322-1331. doi:10.1177/1352458514563591
4. Hobart J, Ziemssen T, Feys P, et al. Assessment of Clinically Meaningful Improvements in Self-Reported Walking Ability in Participants with Multiple Sclerosis: Results from the Randomized, Double-Blind, Phase III ENHANCE Trial of Prolonged-Release Fampridine. *CNS Drugs*. 2019;33(1):61-79. doi:10.1007/s40263-018-0586-5
5. Hupperts R, Gasperini C, Lycke J, et al. Efficacy of prolonged-release fampridine *versus* placebo on walking ability, dynamic and static balance, physical impact of multiple sclerosis, and quality of life: an integrated analysis of MOBILE and ENHANCE. *Ther Adv Neurol Disord*. 2022;15:17562864221090398. Published 2022 May 18. doi:10.1177/17562864221090398
6. Preiningerova JL, Baumhackl U, Csepany T, et al. Recommendations for the use of prolonged-release fampridine in patients with multiple sclerosis (MS). *CNS Neurosci Ther*. 2013;19(5):302-306. doi:10.1111/cns.12101

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