

Reference number(s)
1836-A

SPECIALTY GUIDELINE MANAGEMENT

AMPYRA (dalfampridine) dalfampridine

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Ampyra is indicated as a treatment to improve walking in adult patients with multiple sclerosis. This was demonstrated by an increase in walking speed.

All other indications are considered experimental/investigational and are not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 30 days may be granted to members with a diagnosis of multiple sclerosis if the member has sustained walking impairment (prior to initiating therapy with Ampyra).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted to members with multiple sclerosis if the member has experienced an improvement in walking speed or other objective measure of walking ability since starting Ampyra.

IV. REFERENCES

1. Ampyra [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; November 2021.
2. Dalfampridine [package insert]. Somerset, NJ: Micro Labs USA, Inc.; December 2021.
3. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. *Lancet*. 2009; 373:732-8.