SPECIALTY GUIDELINE MANAGEMENT

AMPYRA (dalfampridine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits 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 patients with multiple sclerosis. This was demonstrated by an increase in walking speed.

All other indications are considered experimental/investigational and are not covered benefits.

II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. History of seizures
B. Creatinine clearance less than or equal to 50 mL/min

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 30 days may be granted to members with multiple sclerosis for improvement in walking when all of the following criteria are met:
A. Member has a diagnosis of multiple sclerosis (MS)
B. Member has sustained walking impairment
C. Member is able to walk at least 25 feet with or without assistance

IV. CONTINUATION OF THERAPY

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

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 20 mg per day.

VI. REFERENCES

1. Ampyra [package insert]. Hawthorne, NY: Acorda Therapeutics, Inc.; January 2014.

2. National Multiple Sclerosis Society. *Disease Management Consensus Statement.* New York, NY: National Multiple Sclerosis Society; 2008. Available at: http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/ExpOp_Consensus.pdf. Accessed April 26, 2016.