



MEDICAL POLICY

Date Reviewed: 04/28/10, 04/15/11

Subject: Ampyra (dalfampridine)

Description: Ampyra, a sustained release tablet, is a potassium channel blocker designed to impede leaks in specialized potassium (K⁺) channels on axons and restore nerve impulses to damaged myelin sheaths. By closing the exposed potassium channels, Ampyra permits the axon to transmit impulses again, even in a demyelinated state.

Indications of Coverage:

The use of Ampyra is considered medically necessary in individuals over the age of 18 when all of the following are met:

Ampyra is prescribed by a neurologist for an individual who has been diagnosed with Multiple Sclerosis

The individual has an Expanded Disability Status Scale (EDSS) score of less than or equal to six and is not restricted to the use of a wheelchair

The documentation does not report a history of seizures or moderate to severe renal impairment

The individual completes a timed 25 foot walk (T25FW) in a period between 8 and 45 seconds

The documentation describes specific limitation in activities of daily living (ADL) related to walking due to Multiple Sclerosis

If criteria are met, treatment may be approved for up to six months. Subsequent treatment may be approved in one year increments with review of continued therapeutic response (defined as a minimum 20% improvement in the timed 25 foot walk and medical record documentation of an improvement in the ability to perform activities of daily living related to walking) and **consistent** prescription medication use.

Dosage and administration: the maximum recommended dose of Ampyra is one 10 mg tablet twice daily, taken with or without food, and should not be exceeded.

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

The use of Ampyra is considered not medically necessary when any of the following are documented:

A history of seizures

Evidence of eliptiform activity on a screening EEG

Onset of a Multiple Sclerosis exacerbation within the previous 60 days (for example, a disturbance in function, such as optic neuritis; an increase in weakness, numbness, spasticity in one or more extremities; bladder dysfunction; trigeminal neuralgia; or loss of muscle coordination, that lasts more than 24 hours)

Documentation required:

Office notes

Laboratory data

Prescription medication use data

Rationale: Although the benefit from the use of Ampyra as documented in clinical trials is small, risks are not well known, and the improvement in walking speed has not yet been demonstrated to be clinically meaningful, the medication has been approved for use as a treatment to improve walking in patients with multiple sclerosis as demonstrated by an increase in walking speed.

References: Ampyra (dalfampridine). Hawthorne, NY: Acorda Therapeutics Inc. Revised: 2010. Available at: www.ampyra.com/local/files/PI.pdf. Accessed: 5 Apr 11.

Goodman AD, Brown TR, Cohen JA, Krupp LB, Schapiro R, Schwid SR, Cohen R, Marinucci LN, Blight AR; Fampridine MS-F202 Study Group. Dose comparison trial of sustained-release fampridine in multiple sclerosis. *Neurology*. 2008 Oct 7; 71(15):1134-41.

Goodman AD, Brown TR, Edwards KR, Krupp LB, Schapiro RT, Cohen R, Marinucci LN, Blight AR; MSF204 Investigators. A phase 3 trial of extended release oral dalfampridine in multiple sclerosis. *Ann Neurol*. 2010 Oct; 68(4):494-502.

Goodman AD, Brown TR, Krupp LB, Schapiro RT, Schwid SR, Cohen R, Marinucci LN, Blight AR; Fampridine MS-F203 Investigators. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. *Lancet*. 2009 Feb 28; 373(9665): 732-8.

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Approved by the Medical Director