MEDICAL POLICY STATEMENT		
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
10/5/2011	**10/5/2012**	**9/22/2011**
Author		
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CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

dalfampridine (Ampyra) Tablets

B. BACKGROUND

Dalfampridine (Ampyra) is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis by enhancing conduction in damaged nerves. In animal studies, dalfampridine has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels.

The patient selection criteria outlined was derived from the FDA-approved prescribing information for dalfampridine (Ampyra), the studies that were presented to the FDA in support of the pre-market approval application, and studies in the peer-reviewed published medical literature. The FDA label indication found in the manufacturer prescribing information and described below is to improve walking ability in patients with multiple sclerosis. Coverage decisions for conditions other than the above FDA approved indications will be reviewed on a case by case basis if proven effective through research documentation. The requesting provider will need to support his exception request with the appropriate literature.

C. POLICY

CareSource will approve the use of dalfampridine (Ampyra), and consider its use as medically necessary when the following criteria have been met for:

- Improved walking ability in multiple sclerosis

All other uses of dalfampridine (Ampyra) are considered experimental/ investigational and therefore, not covered.

Increased Walking Ability in Multiple Sclerosis

Dalfampridine (Ampyra) is indicated as a treatment to improve walking in adult patients (18 years and older) with multiple sclerosis (MS).

Prior Authorization Criteria:

- Documented diagnosis of multiple sclerosis
- Prescribed by a neurologist or under recommendation of a neurologist
- Member has an *Expanded Disability Status Scale* (EDSS) score of less than or equal to 7
  OR
- Is not restricted to utilizing a wheelchair if EDSS not measured
  AND
- Member does not have a history of seizures
- Member does not have moderate or severe renal impairment

Prior Authorization Criteria For Continued Coverage After 12 Weeks:

- Documented diagnosis of multiple sclerosis
- Prescribed by a neurologist or under recommendation of a neurologist
- Member has an *Expanded Disability Status Scale* (EDSS) score of less than or equal to 7
  OR
- Is not restricted to utilizing a wheelchair if EDSS not measured
  AND
- Member does not have a history of seizures
- Member does not have moderate or severe renal impairment
- documented improvement by at least 20% in baseline-timed 25 foot walking speed from pre-treatment measurement.

Note: Documented diagnosis must be confirmed by portions of the individual's medical record, which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

For Medicare

NCD for dalfampridine (Ampyra)

Medicare does not have a National Coverage Determination (NCD) for dalfampridine (Ampyra). In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-

administered by the patients who take them. Refer to the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals at: http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Local Coverage Determinations (LCDs) for dalfampridine (Ampyra) do not exist at this time. (Accessed September 1, 2011)

Safety

CareSource will only review requests for **dalfampridine (Ampyra)** if patient has **none** of the following contraindications:

- History of seizures
- Moderate to severe renal impairment
- Taking other forms of 4-aminopyridine

Pregnancy Risk Factor = C

There are no adequate and well-controlled studies of dalfampridine in pregnant women. Administration of dalfampridine to animals during pregnancy and lactation resulted in decreased offspring viability and growth at doses similar to the maximum recommended human dose (MRHD) of 20 mg/day. Dalfampridine (Ampyra) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether dalfampridine (Ampyra) is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from dalfampridine (Ampyra), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Conditions of Coverage

Quantity Limitations	20mg/day
J-Code	J8499
NDC	10144042760
Applicable ICD-9 Codes	340 Multiple Sclerosis
Place Of Service	Office, Outpatient, Home *****Preferred place of service is in the home*.** **Note:** CareSource supports administering inject able medications in various setting, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the

	most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
Authorization Period	Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. All authorizations are subject to continued eligibility.

D. REVIEW / REVISION HISTORY

10/5/2011

E. REFERENCES

Ampyra [package insert]. Hawthorne, NY: Acorda therapeutics, Inc.; January 2010.

Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2011. (May 30,, 2011)

Goodman AD, Brown TR, Krupp LB,et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet. 2009;373:732-8.

Acorda Therapeutics. Ampyra prescribing information. Available at: http://www.ampyra.com. Accessed on 9/6/11.

Goodman AD, et al. A phase 3 trial of extended release oral dalfampridine in multiple sclerosis. *Ann Neurol*. 2010 Oct; 68(4):494-502.

Chwieduk CM, et al. Dalfampridine extended release: in multiple sclerosis. *CNS Drugs.* 2010 Oct 1; 24(10):883-91.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Chief Medical Officer	October 5, 2011 **Date**
Senior Medical Director	October 5, 2011 **Date**