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PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Dalfampridine (generic for Ampyra)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 60 tabs for 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Dalfampridine (generic for Ampyra) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SYMPTOM MANAGEMENT: WALKING (GAIT) DIFFICULTIES

For **initial** authorization:
If request is for brand name Ampyra, please follow policy "Medical Necessity for DAW" on CareSource webpage.

1. Member must be age 18 or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Member has been on a disease modifying agent (Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Glatopa (glatiramer actate), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Aubagio (teriflunomide), Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Lemtrada (alemtuzumab), Novantrone (mitoxantrone), Tysabri (natalizumab), Ocrevus (ocrelizumab), Mayzent (simponimod) or Mavenclad (cladribine)) for at least the last 90 days; AND
4. Member is ambulatory and has documented baseline of the timed 25 foot walk (T25FW) between 8 and 45 seconds.
5. **Dosage allowed:** 10 mg every 12 hours.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Documentation of member's increase in walking speed submitted with chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Dalfampridine (generic for Ampyra) not medically necessary for the treatment of the following disease states based on a lack of

robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute spinal cord injury
- Disorder of neuromuscular transmission

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.

References:

1. Ampyra [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; October, 2016.
2. Ampyra. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 16, 2017.
3. 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.
4. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.

Effective date: 07/01/2019
Revised date: 05/16/2019