Washington State Health Care Authority

Multiple Sclerosis Agents - dalfampridine

Medical policy no. 62.40.60.30 Effective Date: July 1, 2018

Note:

- *For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.*
  **If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed*
- *If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria*

Background:

Multiple sclerosis (MS) involves an immune-mediated process in which an abnormal response of the body's immune system is directed against the central nervous system (CNS), which is made up of the brain, spinal cord and optic nerves. Within the CNS, the immune system attacks myelin — the fatty substance that surrounds and insulates the nerve fibers — as well as the nerve fibers themselves. The damaged myelin forms scar tissue (sclerosis), which gives the disease its name. When any part of the myelin sheath or nerve fiber is damaged or destroyed, nerve impulses traveling to and from the brain and spinal cord are distorted or interrupted, producing a wide variety of symptoms.

Medical necessity

Drug	Medical Necessity
dalfampridine (AMPYRA®)	Ampyra® may be considered medically necessary when: Used to improve walking in adult patients with multiple sclerosis (MS).

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
dalfampridine (AMPYRA®)	Ampyra® may be covered when ALL of the following are met: 1. Diagnosis of multiple sclerosis (MS) 2. Concurrent use of, documented intolerance, or contraindication of disease modifying agent for MS 3. Greater than or equal to (≥) 18 years of age 4. NONE of the following: a. History of seizures b. Moderate to severe renal insufficiency (CrCl ≤ 50 mL/min) c. Non-ambulatory 5. Prescribed by or in consultation with a neurology specialist 6. Baseline walking speed (timed 25 foot walk (T25W)) or expanded disability status scale (EDSS) 7. Maximum 20mg per day (10mg every 12 hours) **Approve for 6 months**

	Criteria (Reauthorization)
	Documentation of disease stability or lack of disease progression (e.g. improved baseline walking speed (T25W) or EDSS score) **Approve for 12 months**

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
dalfampridine (AMPYRA®)	2 tablets per day; #60 tablets per 30-days

Coding:

ICD-10 Code	Description
G35	Multiple sclerosis

References

1. Product Information: AMPYRA® oral extended-release tablets, dalfampridine oral extended-release tablets. Acorda Therapeutics, Inc. (per FDA), Ardsley, NY, 2017.

History

Date	Action and Summary of Changes
04/18/2018	New Policy