Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran™

AMPYRA™ (dalfampridine)

GPI CODING:

624060300074**

DESCRIPTION:

Dalfampridine (AMPYRA™) is a broad spectrum potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS) demonstrated by an increase in walking speed. Dalfampridine has demonstrated efficacy in all four major types of MS (relapse-remitting, primary-progressive, secondary-progressive, and progressive-relapsing). It may be used alone or with existing MS therapies, including immunomodulator drugs (i.e. AVONEX, BETASERON, COPAXONE, EXTAVIA, NOVANTRONE, REBIF, TYSABRI). The mechanism by which dalfampridine exerts its therapeutic effect is unknown. In animal studies, dalfampridine has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels. The beneficial effects reported in MS patients treated with dalfampridine appear to be related to improvement of nerve conduction and the frequency response in demyelinated nerve fibers via prolongation of the repolarization phase of the action potential. Dalfampridine does not prolong QTc interval and does not have clinically important effects on QRS duration.

APPROVAL DURATION:

Initial approvals: 3 months
Renewals: 12 months
Quantity limit: 2 tabs/day

CRITERIA FOR AMPYRA:

I. Patient has a documented diagnosis of one of the four types of multiple sclerosis (MS) (relapse-remitting, primary-progressive, secondary-progressive, and progressive-relapsing) **AND**
II. Patient is ≥18 years of age **AND**
III. Patient is ambulatory (able to walk with or without an assistive device; at least 25 feet in 8 to 45 seconds) **AND**
IV. Patient does not have a history of seizures **AND**
V. Patient does not have moderate or severe renal impairment (CrCl ≤ 50 mL/min) **AND**
VI. Patient is not currently using any other forms of 4-aminopyridine

Authorization for continued use will be considered when the following criteria are met:

I. Patient is on maintenance therapy with dalfampridine
II. Patient has demonstrated (and prescriber has documented) improvement by:
    a. maintaining a stable walking speed without worsening of ambulation **AND**
    b. at least a 20% improvement in the T25FW from baseline
III. Patient does not have a history of seizures **AND**
IV. Patient does not have moderate or severe renal impairment (CrCl ≤ 50 mL/min) **AND**
V. Patient is not currently using any other forms of 4-aminopyridine