I. Medication Description

Dalfampridine is a broad spectrum potassium channel blocker used to improve walking (gait ataxia) in patients with all subtypes of multiple sclerosis (MS). Approval of dalfampridine to improve walking speed in MS patients was based on the use of a novel endpoint in clinical trials: the Timed 25 Foot Walk test (T25FW), that is, the number of seconds it takes to walk 25 feet. Approximately 30% of patients responded to therapy by demonstrating what is considered a clinically significant improvement of 20% or more on the T25FW test.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Ampyra or dalfampridine is provided in accordance with the following criteria:

- When used to improve walk speed in members with any form of multiple sclerosis AND
- Member is at least 18 years of age AND
- Therapy is prescribed by or under the guidance of a neurologist AND
- Member is receiving concurrent disease modifying therapy (where applicable for form of MS) AND
- Member does not have a history of seizures or evidence of epileptiform activity on EEG AND
- Member has not experienced an MS exacerbation within 60 days of Ampyra or dalfampridine being initiated AND
- Recent progress notes are provided documenting overall disease and ambulatory status (e.g. EDSS, MSWS-12, TUG), medical and medication history, and current MS therapy AND
- At least one baseline Timed 25 Foot Walk Test (T25FW) measured and submitted where the following apply:
  - Measured within 60 days before initiating therapy
  - Walk times are at least 8 seconds and at most 45 seconds
  - Member is not experiencing an acute exacerbation at time of measurement

IV. Quantity Limitations

10mg tablets are covered up to 60 tablets per month.

V. Coverage Duration
• Coverage is initially provided for 3 months and may be renewed.
• Coverage may be renewed in up to 12 month intervals.

VII. Coverage Renewal Criteria

• First Renewal- (after initial 3 month trial) coverage can be renewed for up to 12 months based upon the following:
  o Results of repeat T25FW test (after 3 months of Ampyra/dalfampridine therapy) is submitted and at least a 20% improvement over baseline (pre-treatment) is shown AND
  o Use of assistive devices must be consistent or improved among original and repeat testing to make comparison valid AND
  o Absence of unacceptable toxicity from the drug

• Subsequent Renewals- Coverage can be renewed in up to 12 month intervals based upon documentation of maintenance of at least 20% improvement from T25FW baseline, including:
  o At least two T25FW results measured during office visits in preceding year establishing maintenance of benefit from Ampyra/ dalfampridine (2 separate visits, at least one within 60 days of renewal request) AND
  o Use of assistive devices must be consistent or improved among original and repeat testing to make comparison valid AND
  o Absence of unacceptable toxicity from the drug AND
  o Recent/updated progress notes documenting overall disease status, ambulatory status, impact of Ampyra/ dalfampridine on ambulation, and absence of side effects are provided.

VII. Billing/Coding Information

Available as:
• Ampyra 10mg oral extended release tablets
• dalfampridine 10mg oral extended release tablets

VIII. Summary of Policy Changes

• 12/15/12:
  o Initial criteria for coverage modified to include: 60 day timeframe for T25FW testing, use of disease modifying therapy where applicable, required patient records.
  o Renewal criteria modified to require submission of two T25FW test results during prior year’s treatment period.
  o Required documentation added to each area of policy section.
  o Additional warning regarding seizure side effects and renal considerations added.

• 12/15/13: no policy changes
• 1/1/15: clarification regarding comparison of assistive devices provided
• 7/1/15: formulary distinctions made
• 12/15/15: no policy changes
• 9/15/16: no policy changes
The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.