Pharmacy Benefit Determination Policy

Policy Subject: Multiple Sclerosis Agents	**Dates:**
Policy Number: SHS PBD29	**Effective Date:** August 26, 2010
Category: CNS Agents	**Revision Date:** November 5, 2018
Policy Type: ☒ **Medical** ☒ **Pharmacy**	**Approval Date:** December 5, 2018
Department: Pharmacy	**Next Review Date:** June 2019
Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	PHP: Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Ampyra through the Pharmacy Benefit, and Ocrevus through the Medical Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines.

Drugs and Applicable Coding:

J Code:

Clinical Determination Guidelines:

Document the following with chart notes:

A. Ampyra® oral (dalfampridine)
   1. Age ≥18 years
   2. Prescriber: Neurologist
   3. Diagnosis and severity: MS with documented difficulty walking, resulting in significant limitations of activities of daily living
   4. Walk-speed
      a. Clinical notes documenting 3 measurements and average score.
      b. Timed 25-foot walk speed (T25FW): Baseline 25 feet in 8 - 45 seconds
   5. Other therapies: No prior treatment and failure with Ampyra (non-responder)
   6. Dosage regimen: 10mg oral 2x daily
   7. Approval
      a. Initial approval: 4 months
      b. Re-approval: 6 months; meet all the below:
         - Responder: Shows benefit after the initial 4-month trial period while on medication.
         - Timed 25-foot walk speed (T25FW): Improved/maintained >20% above baseline
         - Significant limitations in activities of daily living: Improved or resolved as a result of increased speed of ambulation as documented in clinical notes
   8. Exclusions:
      a. History of seizures
      b. Moderate to severe renal impairment (CrCl < 50 ml/min)

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Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring & Contraindications	Requirements
Ampyra dalfampridine	• CNS: Asthenia (7%), balance disorder (5%), Dizziness (7%), HA (7%), insomnia (9%) • GI: Nausea (7%) • Misc.: UTI (12%) • Preg.: Adverse events seen in animal repro. studies (↓growth & death)	• Lab: CrCl pre. & annually	• Medication guide

References and Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Ampyra, and Ocrevus, accessed June 2018
2. Disease modifying treatment of relapsing-remitting multiple sclerosis in adults. UpToDate [internet] Accessed May 2016: Available from http://uptodate.com/contents/disease-modifying-treatment-of-relapsing-remittting-multiple-sclerosis-in-adults
3. Effects of dalfampridine Extended-release Tablets on 6-minute walk distance in patients with MS: A post hoc analysis of a double-blind, placebo-controlled trial. Clinical Therapeutics 2015:37(12);2780-87
4. Assessing dalfampridine efficacy in the physician's office. Multiple Sclerosis Journal 2014:20(1);24-26
5. Timed 25-foot walk. American Academy of Neurology 2013:80;1509-17.
6. Challenge of progressive multiple sclerosis therapy. www.co-neurology.com 2017;30(3):237-240

Approved By:

12/5/18

Peter Graham, MD – PHP Executive Medical Director — Date

12/5/18

Human Resources (Kurt Batteen) — Date