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)
Appendix I: Patient Safety and Monitoring

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Reactions</th>
<th>Monitoring &amp; Contraindications</th>
<th>Requirements</th>
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</thead>
</table>
| Ampyra dalfampridine | • CNS: Astenia (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
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

Approved By:

Peter Graham, MD – PHP Executive Medical Director  
12/5/18

Human Resources (Kurt Batteen)  
12/5/18