



SmartPA Criteria Proposal

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|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Drug/Drug Class: | Ampyra Clinical Edit |
| First Implementation Date: | June 30, 2011 |
| Revised Date: | November 19, 2020 |
| Prepared for: | MO HealthNet |
| Prepared by: | MO HealthNet/Conduent |
| Criteria Status: | <input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria |

Executive Summary

Purpose: Ensure appropriate utilization and control of Ampyra® (dalfampridine)

Why Issue Selected: Multiple Sclerosis (MS) is an inflammatory demyelinating disease of the central nervous system that involves a disease course marked by periods of relapse, increasing functional impairment over time, and decreased quality of life. Almost one million people are living with MS in the United States, with most people diagnosed between the ages of 20 and 50 years. The average person in the United States has about a one in 750 chance of developing MS, and it is at least 2–3 times more common in women than in men. Several agents are approved for use in MS to reduce the frequency of relapses and slow disease progression. Ampyra®, FDA approved in 2010, is a broad spectrum potassium channel blocker indicated as a treatment to improve walking in adults with MS, demonstrated by an increase in walking speed. Ampyra is believed to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels. It does come with several warnings, however, including a potential to cause seizures.

| Program-Specific Information: | Date Range FFS 4-1-2019 to 3-31-2020 | | | | |
|-------------------------------|--------------------------------------|--------|-------------|---------------|----------------|
| | Drug | Claims | Spend | Cost per unit | Cost per month |
| | Ampyra® ER 10mg tablet | 221 | \$45,158.99 | \$1.20 NADAC | \$72.00 NADAC |

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Ampyra® (dalfampridine)
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen OR
- Adequate therapeutic trial of 2 different multiple sclerosis agents in the past 2 years AND

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- Documented diagnosis of Multiple Sclerosis (MS) AND
- Claim does not exceed 2 tablets per day

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented diagnosis of seizures
- Documented diagnosis of moderate to severe renal insufficiency

Required Documentation

| | | | |
|---------------------|--------------------------|-----------------|-------------------------------------|
| Laboratory Results: | <input type="checkbox"/> | Progress Notes: | <input type="checkbox"/> |
| MedWatch Form: | <input type="checkbox"/> | Other: | <input checked="" type="checkbox"/> |

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
 Rule Type: CE

Default Approval Period

1 year

References

- AMPYRA (dalfampridine) extended release tablets [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; September 2017.
- American Academy of Neurology. Comprehensive Systematic Review Summary: Disease-Modifying Therapies for Adults with Multiple Sclerosis. https://cdn-links.lww.com/permalink/wnl/a/wnl_2018_04_19_raegrant_neurology2017835181r1_sdc3.pdf. April 2018.
- Levin, Michael C. Multiple Sclerosis (MS). <https://www.merckmanuals.com/professional/neurologic-disorders/demyelinating-disorders/multiple-sclerosis-ms>. December 2019.
- IPD Analytics. New Drug Review: Zeposia (ozanimod). May 2020.