Clinical Edit Criteria Proposal

Drug/Drug Class: Ampyra Clinical Edit
Date: June 30, 2011
Prepared for:
Prepared by: MO HealthNet

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

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

Why was this Issue Selected: Multiple Sclerosis (MS) is an inflammatory demyelinating disease of the central nervous system that is associated with many chronic symptoms. MS is an immune-mediated disorder of acute, repeated episodes of inflammation causing destruction of the myelin sheath and axonal loss. This process leads to chronic multifocal sclerotic plaques and eventually, progressive neurological dysfunction. Multiple Sclerosis is the most common cause of neurological disability in young adults, affecting 250,000 to 350,000 people in the U.S. The lifetime risk of MS is 1 in 400. MS affects twice as many women as men, as is often observed in autoimmune diseases. Multiple Sclerosis agents are used to reduce the frequency of relapses and slow disease progression. Ampyra is a broad-spectrum potassium channel blocker, and the first MS medication thought to enhance signal conduction in the nerves by blocking some of the potassium leaks. This medication is indicated as a treatment to improve walking in people with MS, demonstrated by an increase in walking speed.

Program-specific information:	**Drug**	**Claims**	**Expenses**
	• Ampyra®	81	*$90,201*

Setting & Population: All Patients

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**

☒ **Appropriate Indications** ☐

Data Sources:	☐ **Only administrative databases**	☒ **Databases + Prescriber-supplied**

Setting & Population

- Drug for review: Ampyra (dalfampridine)
- Age range: All Patients
- Gender: Males and Females

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on **2 preferred Multple Sclerosis Agents**
  - Documented trial period for preferred agents
  - Documented ADE/ADR to preferred agents
- Documented compliance on current therapy regimen

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- Presence of seizure history
- Renal Insufficiency (Moderate to Severe)
  - CrCl < 50ml/min

References

1. Facts and Comparisons Online; 2010.
2. USPDI, Micromedex, 2010.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
4. Acordia Therapeutics, Inc., “Ampyra Package Insert”, Hawthorne, NY, 10532; 2010.