SmartPA Criteria Proposal

Drug/Drug Class:	Multiple Sclerosis, Oral Agents PDL Edit
First Implementation Date:	January 6, 2011
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why 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 the 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. Most agents are FDA approved for the treatment of relapsing forms of MS. The American Academy of Neurology does not recommend a specific first-line agent for MS and state participant factors regarding safety, route of administration, cost, and efficacy should be considered when deciding which agent to initiate.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Aubagio®** • Gilenya®**	• Mavenclad® • Mayzent® • Tecfidera® • Vumerity™
**Pending trial of one injectable agent	

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

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Multiple Sclerosis, Oral Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- For Gilenya and Aubagio: documented trial on 1 injectable biologic agent (6 months) **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents by one or more of the following:
  - 1 or more relapses
  - 1 or more new MRI lesions
  - Participant demonstrates increased disability on a clinical rating scale such as the Expanded Disability Status Scale (EDSS) or the Functional Systems Score (FSS)
  - Documented trial period of preferred agents (6 months)
  - Documented ADE/ADR to preferred agents **AND**
- For Mayzent:
  - Participants aged ≥ 18 years or older **AND**
  - Prescribed by or in consultation with a neurologist or other appropriate specialist for the disease state **AND**
  - Documented diagnosis of MS **AND**
  - Absence of:
    - The following conditions in the past 6 months: MI, unstable angina, stroke, TIA **AND**
    - Mobitz type II second, third degree AV block, or sick sinus syndrome without a functioning pacemaker in the past 2 years **AND**
  - Prior to therapy: CYP2C9 Genotype determination, CBC, ophthalmic evaluation, electrocardiogram, LFTs and test for varicella zoster virus antibodies **OR**
- For Mavenclad:
  - Participants aged ≥ 18 years or older **AND**
  - Prescribed by or in consultation with a neurologist or other appropriate specialist for the disease state **AND**
  - Documented diagnosis of MS **AND**
  - Absence of the following: history of malignancy, pregnancy/breastfeeding, HIV and concurrent use of other disease modifying therapies **AND**
  - Prior to therapy: CBC with lymphocytes (lymphocytes must be normal prior to first treatment course, and at least 800 cells per microliter before the second treatment course), tuberculosis screening, hepatitis B and C screening, presence of acute infections, vaccination with varicella zoster vaccine in those who are antibody negative, baseline MRI and LFTs **AND**
- **For Vumerity: documented trial of Tecfidera (clinical consultant review)**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
MAVENCLAD	CLADRIBINE	4 boxes per year

Required Documentation

Laboratory Results:	X	Progress Notes:	
MedWatch Form:		Other:	

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. Evidence-Based Medicine and Fiscal Analysis: “Multiple Sclerosis Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; April 2020.
5. Evidence-Based Medicine Analysis: “Multiple Sclerosis (MS) Agents”, UMKC-DIC; April 2020.
6. American Academy of Neurology: Practice Guideline Recommendations Summary: Disease-Modifying Therapies for Adults with Multiple Sclerosis. Available at URL: https://www.aan.com/Guidelines/home/GuidelineDetail/898.
7. Drug Effectiveness Review Project: Drug Class Review – Disease-Modifying Drugs for Multiple Sclerosis; Oregon Health & Science University, September 2013; updated May 2016.