SmartPA Criteria Proposal

Drug/Drug Class:	Multiple Sclerosis Agents, Injectable PDL Edit
First Implementation Date:	January 6, 2011
Proposed Date:	September 15, 2022
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. However, Ocrevus® (ocrelizumab) is also approved for primary progressive 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
• Avonex® • Copaxone® 20 mg, 40 mg Syringe • **Kesimpta®**** • Rebif® • Rebif® Rebidose®	• Betaseron® **Kit**/Vial • Extavia® • Glatiramer • Glatopa® • Lemtrada® • Ocrevus® • Plegridy® • Tysabri®
***Pending trial of one injectable biologic agent or Gilenya®*	

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 Agents, Injectable
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- **For Kesimpta:**
  - **Documented 6 month therapeutic trial on 1 injectable biologic agent OR**
  - **Documented 6 month therapeutic trial of Gilenya**
- Requests for non-preferred agents:
  - 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 ADE/ADR to preferred agents **OR**
  - For Ocrevus with a documented diagnosis of primary progressive MS in the past 6 months:
    - Documented 6 month therapeutic trial on 1 injectable biologic agent **OR**
    - **Documented 6 month therapeutic trial of Gilenya**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

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

- Evidence-Based Medicine Analysis: “Multiple Sclerosis (MS) Agents”, UMKC-DIC; March 2022.
- Evidence-Based Medicine and Fiscal Analysis: “Multiple Sclerosis Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- 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.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.