

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Multiple Sclerosis, Injectable Agents PDL Edit
<b>First Implementation Date:</b>	January 6, 2011
<b>Proposed Date:</b>	June 18, 2020
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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
<ul style="list-style-type: none"> <li>• Betaseron® Kit</li> <li>• Copaxone® 20mg Syringe</li> <li>• Rebif®</li> <li>• Rebif® Rebidose®</li> </ul>	<ul style="list-style-type: none"> <li>• Avonex®</li> <li>• Betaseron® Vial</li> <li>• Copaxone® 40mg Syringe</li> <li>• Extavia®</li> <li>• Glatiramer</li> <li>• Glatopa™</li> <li>• Lemtrada®</li> <li>• Ocrevus™</li> <li>• Plegridy®</li> <li>• Tysabri®</li> </ul>

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

## Approval Criteria

- Documented compliance on current therapy regimen **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 **OR**
- For Ocrevus:
  - Documented diagnosis of primary progressive MS in the past 6 months **AND**
  - Documented trial on 1 injectable biologic agent (6 months)

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
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.

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### *SmartPA PDL Proposal Form*

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