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:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
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<tbody>
<tr>
<td>Aubagio®**</td>
<td>Mavenclad®</td>
</tr>
<tr>
<td>Dimethyl Fumarate**</td>
<td>Mayzent®</td>
</tr>
<tr>
<td>Gilenya®**</td>
<td>Tecfidera®</td>
</tr>
<tr>
<td></td>
<td>Vumery™</td>
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<tr>
<td></td>
<td>Zeposia®</td>
</tr>
</tbody>
</table>

**Pending trial of one injectable agent

Type of Criteria: ☒ Preferred Drug List

Data Sources: ☒ 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 preferred agents: 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:
    - 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 Tecfidera (brand) and Vumerity: Clinical consultant review for medical necessity
- For Zeposia:
  - 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
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:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dosing Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAVENCLAD</td>
<td>CLADRIBINE</td>
<td>4 boxes per year</td>
</tr>
<tr>
<td>ZEPOSIA 0.92 MG</td>
<td>OZANIMOD HYDROCHLORIDE</td>
<td>1 capsule per day</td>
</tr>
</tbody>
</table>

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

2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
7. Drug Effectiveness Review Project: Drug Class Review – Disease-Modifying Drugs for Multiple Sclerosis; Oregon Health & Science University, September 2013; updated May 2016.