SmartPA Criteria Proposal

Drug/Drug Class:	Multiple Sclerosis Agents, Oral PDL Edit
First Implementation Date:	January 6, 2011
Proposed Date:	June 17, 2021
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 states 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®**	• **Bafiertam®**
• **Dimethyl fumarate**	• Mavenclad®
• Gilenya®**	• Mayzent®
	• **Ponvory™**
	• Tecfidera®
	• Vumerity®
	• **Zeposia®**
Pending trial of one injectable agent **or generic Tecfidera	

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, Oral
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- For **Aubagio and Gilenya**: documented 6 month therapeutic trial on 1 injectable biologic agent or **generic Tecfidera** **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) **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Mavenclad, Mayzent, **and Ponvory**:
  - Participant aged ≥ 18 years or older **AND**
  - Prescribed by or in consultation with a neurologist or other appropriate specialist for the treated disease state **AND**
  - Documented diagnosis of multiple sclerosis **AND**
  - For Mavenclad – 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
  - For Mayzent – prior to therapy: CYP2C9 Genotype determination, CBC, ophthalmic evaluation, electrocardiogram, LFTs and test for varicella zoster virus antibodies
  - **For Ponvory – prior to therapy: CBC with lymphocytes (within 6 months or after discontinuation of prior therapy), electrocardiogram, LFTs (within last 6 months), ophthalmic evaluation, vaccination with varicella zoster vaccine in those who are antibody-negative**
- **For Zeposia:**
  - **Participant aged ≥ 18 years or older AND**
  - **For multiple sclerosis:**
    - **Documented diagnosis of multiple sclerosis AND**
    - **Prescribed by or in consultation with a neurologist or other appropriate specialist for the disease state**
  - **For ulcerative colitis:**
    - **Adequate therapeutic trial on 3 preferred Ulcerative Colitis, Oral agents AND**
    - **Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitor defined as:**
      - **Combination therapy of 2 TNF inhibitors OR**
      - **Monotherapy of 1 TNF inhibitor AND**
  - **Prior to therapy: CBC with lymphocytes (within 6 months or after discontinuation of prior multiple sclerosis or ulcerative colitis therapy), electrocardiogram, LFTs (within last 6 months), ophthalmic evaluation, vaccination with varicella zoster vaccine in those who are antibody-negative**
- **For brand Tecfidera** and Vumerity: Clinical consultant review for medical necessity

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- For Mavenclad: history of malignancy, pregnancy/breastfeeding, HIV and concurrent use of other disease modifying therapies
- For Mayzent, **Ponvory**, and Zeposia: presence of MI, unstable angina, stroke, TIA, **decompensated heart failure (HF) requiring hospitalization, or Class III or IV HF** in the past 6 months, or Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, **or sino-atrial block** without a functioning pacemaker in the past 2 years
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
AUBAGIO 7 MG TABLET	TERIFLUNOMIDE	1 tablet per day
AUBAGIO 14 MG TABLET	TERIFLUNOMIDE	1 tablet per day
BAFIERTAM DR 95 MG CAPSULE	MONOMETHYL FUMARATE	4 capsules per day
GILENYA 0.25 MG CAPSULE	FINGOLIMOD	1 capsule per day
GILENYA 0.5 MG CAPSULE	FINGOLIMOD	1 capsule per day
MAVENCLAD 10 MG TABLET	CLADRIBINE	4 boxes per year
MAYZENT 2 MG TABLET	SIPONIMOD	1 tablet per day
PONVORY 20 MG TABLET	PONESIMOD	1 tablet per day
TECFIDERA DR 120 MG CAPSULE	DIMETHYL FUMARATE	2 capsules per day
TECFIDERA DR 240 MG CAPSULE	DIMETHYL FUMARATE	2 capsules per day
VUMERTIY DR 231 MG CAPSULE	DIPROXIMEL FUMARATE	4 capsules per day
ZEPOSIA 0.92 MG CAPSULE	OZANIMOD HCL	1 capsule per day

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. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Evidence-Based Medicine and Fiscal Analysis: “Multiple Sclerosis Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
4. Evidence-Based Medicine Analysis: “Multiple Sclerosis (MS) Agents”, UMKC-DIC; March 2021.
5. 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.

6. Drug Effectiveness Review Project: Drug Class Review – Disease-Modifying Drugs for Multiple Sclerosis; Oregon Health & Science University, September 2013; updated May 2016.
7. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation, April 2021.
8. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC.; April 2020.
9. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation, December 2019.
10. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; April 2019.
11. Mayzent [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2021.
12. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2021.
13. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; January 2021.
14. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; January 2021.
15. Zeposia [package insert]. Summit, NJ: Celgene Corporation; May 2021.