SmartPA Criteria Proposal

Drug/Drug Class:	Multiple Sclerosis Agents, Oral PDL Edit
First Implementation Date:	January 6, 2011
Proposed Date:	July 18, 2023
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, lifestyle, cost, efficacy, common adverse events, and tolerability 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
• Dimethyl Fumarate • **Fingolimod**	• Aubagio® • Bafiertam® • **Gilenya® 0.25 mg*** • **Gilenya® 0.5 mg** • Mavenclad® • Mayzent® • Ponvory® • Tascenso ODT™ • Tecfidera® • **Teriflunomide (gen Aubagio®)** • Vumerity® • Zeposia®
***Available to participants < 18 years of age without any pre-requisite therapy**	

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☒ **Appropriate Indications**	☐ **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**
- Claim is for ~~**generic Tecfidera**~~ **a preferred agent** **OR**
- ~~**For Gilenya:**~~
  - ~~**Participant is aged < 18 years and claim is for 0.25 mg per day OR**~~
  - ~~**Documented 6 month therapeutic trial on 1 injectable biologic agent or generic Tecfidera or evidence of highly active disease OR**~~
- Requests for non-preferred agents:
  - For documented diagnosis of multiple sclerosis:
    - 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 Vumerity: Clinical Consultant Review for medical necessity
    - **For Gilenya 0.25mg: Participant is aged < 18 years**
    - For Mavenclad, Mayzent, Ponvory, and Zeposia:
      - 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**
      - Prior to Mavenclad therapy:
        - Cancer screening
        - 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
        - Lack of acute infections
        - Vaccination with varicella zoster vaccine
        - LFTs (within last 6 months)
        - Baseline MRI
      - Prior to Mayzent, Ponvory, and Zeposia therapy:
        - CYP2C9 Genotype determination (Mayzent only)
        - CBC with lymphocytes (within 6 months or after discontinuation of prior therapy).
        - Ophthalmic evaluation
        - Electrocardiogram
        - LFTs (within last 6 months)
        - Lack of acute infections
        - Vaccination with varicella zoster vaccine in those who are antibody negative

        - **Skin examination for cutaneous malignancies**
    - For documented diagnosis of ulcerative colitis:
        - Claim is for Zeposia **AND**
        - Prior to Zeposia therapy:
            - CBC with lymphocytes (within 6 months or after discontinuation of prior therapy).
            - Ophthalmic evaluation
            - Electrocardiogram
            - LFTs (within last 6 months)
            - Lack of acute infections
            - Vaccination with varicella zoster vaccine in those who are antibody negative
            - **Skin examination for cutaneous malignancies** **AND**
        - Adequate therapeutic trial on 3 preferred oral Inflammatory Bowel Disease Agents **AND**
        - Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitor (trial defined as duration of therapy with class not agent)

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Mavenclad:
    - History of malignancy or HIV
    - Participant is currently pregnant
    - Concurrent use of other disease modifying therapies
- For Mayzent, Ponvory, and Zeposia:
    - Participant is currently pregnant
    - Presence of MI, unstable angina, stroke, TIA, decompensated heart failure (HF) requiring hospitalization, or Class III or IV HF in the past 6 months
    - Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome or sino-atrial block without a functioning pacemaker
- Therapy will be denied if all approval criteria are not met
- 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 0.25 MG TABLET	SIPONIMOD	5 tablets per day
MAYZENT 1 MG TABLET	SIPONIMOD	1 tablet per day
MAYZENT 2 MG TABLET	SIPONIMOD	1 tablet per day
PONVORY 20 MG TABLET	PONESIMOD	1 tablet per day
TASCENSO ODT 0.25 MG TABLET	FINGOLIMOD LAURYL SULFATE	1 tablet per day
TASCENSO ODT 0.5 MG TABLET	**FINGOLIMOD LAURYL SULFATE**	**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

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: Multiple Sclerosis Agents, Oral”, Gainwell Technologies; Last updated May 3, 2023.
- Evidence-Based Medicine Analysis: “Central Nervous System: Multiple Sclerosis (MS), Injectable Agents”, UMKC-DIC; February 2023.
- 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.
- Rae-Grant A, Day GS, Marrie RA, et. al. American Academy of Neurology. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis, April 2018. Summary of Evidence-Based Guideline: Complementary and Alternative Medicine in Multiple Sclerosis (aan.com).
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.