Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2020**
Policy Number: PHW.PDL.043	**Effective Date: 01/05/2021** **Revision Date: 11/2020**
Policy Name: Multiple Sclerosis Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021: policy revised according to DHS revisions effective 01/05/2021

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Multiple Sclerosis Agents

Reference Number: PHW.PDL.043
Effective Date: 01/01/2020
Last Review Date: 11/2020

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Multiple Sclerosis Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Multiple Sclerosis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Multiple Sclerosis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Multiple Sclerosis Agent. See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: https://papdl.com/preferred-drug-list.

2. A prescription for Ampyra (dalfampridine), Aubagio (teriflunomide), Gilenya (fingolimod), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate).

3. A Multiple Sclerosis Agent with a prescribed quantity that exceeds the quantity limit.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Multiple Sclerosis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Tysabri (natalizumab), see PHW.PDL.043.01 Natalizumab (Tysabri); **OR**

2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**

3. Is prescribed the Multiple Sclerosis Agent by **one** of the following:

   a. For Ampyra (dalfampridine), a neurologist or physical medicine and rehabilitation (PM&R) specialist
   b. For all other Multiple Sclerosis Agents, a neurologist;

AND

4. Does not have a history of a contraindication to the prescribed Multiple Sclerosis Agent; **AND**

5. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

6. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature; **AND**

7. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

8. For a non-preferred Multiple Sclerosis Agent, **one** of the following:

    a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary's diagnosis

    b. **One** of the following:

        i. Has a current prescription (within the past 90 days) for the same non-preferred Multiple Sclerosis Agent
        ii. For a non-preferred Multiple Sclerosis Agent with a dosing interval exceeding 90 days (e.g., Lemtrada, Mavenclad, Ocrevus), is receiving treatment with the same non-preferred Multiple Sclerosis Agent and will continue therapy at a dosing interval supported by FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature;

AND

9. For Lemtrada (alemtuzumab), **all** of the following:

    a. Has documented positive antibodies for varicella zoster virus (VZV), documentation of vaccination for VZV, or a healthcare professional confirmed history of chickenpox,
    b. Did not receive a VZV vaccination in the previous six weeks,
    c. Has documentation of a recent negative purified protein derivative (PPD) test or blood test for tuberculosis;

AND

10. For Ampyra (dalfampridine), has motor dysfunction on a continuous basis that impairs the ability to complete instrumental activities of daily living (IADL's) or

activities of daily living (ADL's); **AND**

11. For Aubagio (teriflunomide), **both** of the following:

    a. Does not have a diagnosis of severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection
    b. Has documentation of a recent negative purified protein derivative (PPD) test or blood test for tuberculosis;

    AND

12. For Gilenya (fingolimod), **both** of the following:

    a. Has documented positive antibodies to VZV, documentation of vaccination for VZV, or a healthcare professional confirmed history of chickenpox
    b. Did not receive a VZV vaccination in the previous one month;

    AND

13. For Ocrevus (ocrelizumab), does not have evidence of significant active infection; **AND**

14. For Mavenclad (cladribine), **both** of the following:

    a. Has documentation of recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the first treatment course
    b. Has documented positive antibodies to VZV, documentation of vaccination for VZV, or a healthcare professional confirmed history of chickenpox;

    AND

15. For Mayzent (siponimod), **both** of the following:

    a. Has documented positive antibodies to VZV, documentation of vaccination for VZV, or a healthcare professional confirmed history of chickenpox
    b. Has documentation of prescriber consultation with a cardiologist if recommended in the FDA-approved package labeling;

    AND

16. For Zeposia (ozanimod), has documented positive antibodies to VZV, documentation of vaccination for VZV, or a healthcare professional confirmed history of chickenpox; **AND**

17. If a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the

quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MULTIPLE SCLEROSIS AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Multiple Sclerosis Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed the Multiple Sclerosis Agent by **one** of the following:

    a. For Ampyra (dalfampridine), a neurologist or physical medicine and rehabilitation (PM&R) specialist
    b. For all other Multiple Sclerosis Agents, a neurologist;

    AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a history of a contraindication to the prescribed Multiple Sclerosis Agent; **AND**

4. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

5. **One** of the following:

    a. For Ampyra (dalfampridine), has a documented improvement in motor function

    b. For all other Multiple Sclerosis Agents, **one** of the following:

        i. For a Multiple Sclerosis Agent prescribed for a diagnosis of a relapsing form of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course
        ii. For a Multiple Sclerosis Agent prescribed for a diagnosis of primary progressive multiple sclerosis, based on the prescriber's professional judgement, continues to benefit from the prescribed Multiple Sclerosis Agent;

AND

6. For Lemtrada (alemtuzumab), **both** of the following:

   a. Received the previous treatment course at least 12 months prior to the requested treatment course with Lemtrada (alemtuzumab)
   b. Does not have signs of malignancy or autoimmune disorder;

   AND

7. For Aubagio (teriflunomide), does not have a diagnosis of severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection; **AND**

8. For Ocrevus (ocrelizumab), does not have evidence of significant active infection; **AND**

9. For Mavenclad (cladribine), **both** of the following:

   a. Has documentation of recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the second treatment course
   b. Has not exceeded the recommended total number of treatment courses according to FDA-approved package labeling;

   AND

10. For Mayzent (siponimod), has documentation of prescriber consultation with a cardiologist if recommended in the FDA-approved package labeling;

    AND

11. If a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

    NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Multiple Sclerosis Agent. If the guidelines in Section B. are met, the reviewer will

prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Multiple Sclerosis Agents will be approved as follows:

1. For Ampyra (dalfampridine) or Aubagio (teriflunomide):

   a. Initial requests will be approved for 3 months.
   b. Renewal requests will be approved for 6 months.

2. For Lemtrada (alemtuzumab):

   a. Requests for an **initial** treatment course will be approved for 5 days.
   b. Requests for **subsequent** treatment courses will be approved for 3 days.

3. For Mavenclad (cladribine):

   a. PA Health & Wellness will limit authorizations consistent with FDA-approved package labeling.

4. For all other agents:
   - New Request: 6 months
   - Renewal Request: 12 months

E. References:

1. Ampyra Package Insert. Ardsley, NY: Acorda Therapeutics, Inc.; December 2019.
2. Aubagio Package Insert. Cambridge, MA: Genzyme Corporation; February 2020.
3. Clinical Resource, Multiple Sclerosis Treatments, The Pharmacists Letter/Prescriber's Letter. September 2017.
4. Gilenya Package Insert. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; December 2019.
5. Hauser SL, Bar-Or A, Comi G, et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. New England Journal of Medicine. January 19, 2017; 376:221-234.
6. Lemtrada Package Insert. Cambridge, MA: Genzyme Corporation; May 2020.
7. Mavenclad Package Insert. Rockland, MA: EMD Serono, Inc.; March 2019.
8. Mayzent Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

9. MedWatch FDA Safety Information and Adverse Event Reporting Program, Gilenya (fingolimod): Drug Safety Communication - Safety Review of a Reported Death After the First Dose, May 2012.
10. Montalban X, Hauser SL, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. New England Journal of Medicine. January 19, 2017. 376:209-220.
11. Ocrevus (ocrelizumab) Package Insert. South San Francisco, CA: Genetech, Inc.; May 2020.
12. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated June 3, 2020. Accessed July 9, 2020.
13. Olek MJ, Mowry E. Treatment of progressive multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated May 18, 2020. Accessed July 9, 2020.
14. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology 2018; 90:777.
15. Tecfidera Package Insert. Cambridge, MA: Biogen Inc.; February 2020.
16. Vumerity Package Insert. Waltham, MA: Alkermes, Inc.; October 2019.
17. Zeposia Package Insert.Summit, NJ: Celgene Corporation; March 2020.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020