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: 11/2021**
Policy Number: PHW.PDL.043	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
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 2022: revised according to DHS revisions effective 01/03/2022

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Multiple Sclerosis Agents

Reference Number: PHW.PDL.043
Effective Date: 01/01/2020
Last Review Date: 10/2021

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 member:

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

2. For Zeposia (ozanimod), see PHW.PDL.043.02 Ozanimod (Zeposia); **OR**

3. 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**

4. 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

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

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

7. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature; **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 member'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 (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)
      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 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**

10. For Mavenclad (cladribine), has documentation of a recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the first treatment course; **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 member 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 member, 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 member:

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

    a. For Ampyra (dalfampridine ER), a neurologist or 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 contraindication to the prescribed Multiple Sclerosis Agent; **AND**

4. **One** of the following:

    a. For Ampyra (dalfampridine ER), 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

5. For Lemtrada (alemtuzumab), received the previous treatment course at least 12 months prior to the requested treatment course with Lemtrada (alemtuzumab); **AND**

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

    a. Has documentation of a 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

7. 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 member 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 member, 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 member.

D. Dose and Duration of Therapy

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

1. For Ampyra (dalfampridine ER) 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 up to 3 days.

3. For Mavenclad (cladribine):

   a. Requests for prior authorization will be approved for a duration of therapy 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.; February 2021.
2. Aubagio Package Insert. Cambridge, MA: Genzyme Corporation; April 2021.
3. Bafiertam Package Insert. High Point, NC: Banner Life Sciences; April 2020.
4. Clinical Resource, Multiple Sclerosis Treatments, The Pharmacists Letter/Prescriber's Letter. September 2017.
5. Gilenya Package Insert. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; December 2019.
6. 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.
7. Kesimpta Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.
8. Lemtrada Package Insert. Cambridge, MA: Genzyme Corporation; April 2021.
9. Mavenclad Package Insert. Rockland, MA: EMD Serono, Inc.; March 2019.
10. Mayzent Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2021.
11. 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.
12. Ocrevus (ocrelizumab) Package Insert. South San Francisco, CA: Genetech, Inc.; December 2020.
13. Olek MJ, Mowry E. Disease-modifying therapies for multiple sclerosis: Pharmacology administration, and adverse effects. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated May 11, 2021. Accessed July 15, 2021.
14. Olek MJ, Mowry E. Initial disease-modifying therapy for relapsing-remitting multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated June 4, 2021. Accessed July 15, 2021.
15. Olek MJ, Mowry E. Treatment of primary progressive multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated December 8, 2020. Accessed July 15, 2021.
16. Olek MJ, Mowry E. Treatment of secondary progressive multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated April 26, 2021. Accessed July 15, 2021.
17. Ponvory Package Insert. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021.
18. 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.
19. Tecfidera Package Insert. Cambridge, MA: Biogen Inc.; January 2021.
20. Vumerity Package Insert. Cambridge, MA: Biogen Inc.; January 2021.

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
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021