

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
MULTIPLE SCLEROSIS AGENTS

**Proposed Effective Date:** January 5, 2026

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

**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 Multiple Sclerosis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for Ampyra (dalfampridine ER), Aubagio (teriflunomide), Briumvi (ublituximab-xiiy), Gilenya (fingolimod), Kesimpta (ofatumumab), Ocrevus (ocrelizumab), **Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)**, Tysabri (natalizumab), or Tecfidera (dimethyl fumarate DR).

B. Revisions to 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 a natalizumab product, see the prior authorization guideline related to Natalizumab; **OR**
2. For Zeposia (ozanimod) for the treatment of ulcerative colitis, see the prior authorization guideline related to Ulcerative Colitis Agents; **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 age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **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 prescribed the Multiple Sclerosis Agent by **one** of the following:

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
MULTIPLE SCLEROSIS AGENTS

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

**AND**

- 7. Does not have a contraindication to the prescribed Multiple Sclerosis Agent; **AND**
- 8. For a non-preferred Multiple Sclerosis Agent, **one** of the following:
  - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Multiple Sclerosis Agents approved or medically accepted 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 (does not apply to non-preferred Multiple Sclerosis Agents when a therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic is preferred ~~does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred~~)
    - ii. For a non-preferred Multiple Sclerosis Agent with a dosing interval exceeding 90 days (e.g., Lemtrada, Mavenclad), 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 medical literature;

**AND**

- 9. For Ampyra (dalfampridine ER), has motor dysfunction on a continuous basis that impairs the ability to complete instrumental activities of daily living or activities of daily living; **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 the Quantity Limits Chapter.

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

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
MULTIPLE SCLEROSIS AGENTS

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

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 **or a non-relapsing form of secondary progressive multiple sclerosis**, continues to benefit from the prescribed Multiple Sclerosis Agent based on the prescriber's assessment;

**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;

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
MULTIPLE SCLEROSIS AGENTS

**AND**

7. For a non-preferred Multiple Sclerosis Agent with a therapeutically equivalent ~~brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic~~ **brand/generic or corresponding biosimilar/brand biologic/unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic** that would not be expected to occur with the requested drug; **AND**
8. 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 the Quantity Limits Chapter.

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. Revisions to 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 up to three months.
  - b. Renewal requests will be approved for up to six months.
2. For Lemtrada (alemtuzumab):
  - a. Requests for an initial treatment course will be approved for up to five days.
  - b. Requests for subsequent treatment courses will be approved for up to three days.

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
MULTIPLE SCLEROSIS AGENTS

3. For Mavenclad (cladribine):

- a. Requests for prior authorization will be approved for a duration of therapy consistent with FDA-approved package labeling.

E. References:

1. Ampyra Package Insert. Pearl River, NY: Acorda Therapeutics, Inc.; June 2022.
2. Aubagio Package Insert. Cambridge, MA: Genzyme Corporation; ~~December 2022~~ **June 2024.**
3. Bafiertam Package Insert. High Point, NC: Banner Life Sciences; ~~January 2023~~ **March 2024.**
4. Briumvi Package Insert. Morrisville, NC: TG Therapeutics, Inc.; ~~December 2022~~ **November 2024.**
5. Clinical Resource, Multiple Sclerosis Treatments, The Pharmacists Letter/Prescriber's Letter. September 2017.
6. Gilenya Package Insert. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; ~~July 2022~~ **June 2024.**
7. 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.
8. Kesimpta Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; ~~September 2022~~ **April 2024.**
9. Lemtrada Package Insert. Cambridge, MA: Genzyme Corporation; May 2024~~3.~~
10. Mavenclad Package Insert. Rockland, MA: EMD Serono, Inc.; ~~September 2022~~ **May 2024.**
11. Mayzent Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; ~~January 2023~~ **June 2024.**
12. 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.
13. Ocrevus (ocrelizumab) Package Insert. South San Francisco, CA: Genetech, Inc.; ~~March 2023~~ **June 2024.**
14. **Ocrevus Zunovo Package Insert. South San Francisco, CA: Genetech, Inc.; September 2024.**
15. Olek MJ, Mowry E. **Overview of Disease-modifying therapies for multiple sclerosis: Pharmacology, administration, and adverse effects.** Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated ~~March 15, 2023~~ **April 28, 2025.** Accessed August 01~~9~~, 202~~5~~~~3~~.
16. 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 22, 2022~~ **January 10, 2025.** Accessed August 01~~9~~, 202~~5~~~~3~~.
17. Olek MJ, Mowry E. Treatment of primary progressive multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated ~~August 22, 2022~~ **January 10, 2025.** Accessed August 01~~9~~, 202~~5~~~~3~~.
18. Olek MJ, Mowry E. Treatment of secondary progressive multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated ~~April 12, 2023~~

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
MULTIPLE SCLEROSIS AGENTS

**May 05, 2025**. Accessed August **19, 2025**.

19. Ponvory Package Insert. Titusville, NJ: Janssen Pharmaceuticals, Inc.; ~~September 2022~~  
**August 2023**.
20. 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.
21. Tascenso ODT Package Insert. ~~Cambridge~~ **Swindon**, United Kingdom: ~~Cycle-Pharmaceuticals Ltd~~ **Catalent Pharmaceuticals Ltd**; ~~December 2022~~ **January 2025**.
22. Tecfidera Package Insert. Cambridge, MA: Biogen Inc.; ~~February 2023~~ **March 2024**.
23. Vumerity Package Insert. Cambridge, MA: Biogen Inc.; ~~February 2023~~ **September 2024**.
24. Zeposia Package Insert. Princeton, NJ: Bristol-Myers Squibb Company; August 202**4**.