pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 12, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Multiple Sclerosis Agents – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Multiple Sclerosis Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Multiple Sclerosis Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Multiple Sclerosis Agents to the appropriate MCO.

BACKGROUND:

*01-21-35	09-21-34	27-21-26	33-21-34
02-21-22	11-21-24	30-21-29	
03-21-22	14-21-25	31-21-37	
08-21-37	24-21-32	32-21-22	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Multiple Sclerosis Agents:

- Addition of a guideline for Zeposia (ozanimod) that refers to the Zeposia (ozanimod) prior authorization guidelines;
- Deletion of the guidelines that the beneficiary 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);
- Clarification of the guidelines for a non-preferred Multiple Sclerosis Agent that a current history of being prescribed 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;
- Deletion of all guidelines for varicella zoster testing and vaccination;
- Deletion of all guidelines for tuberculosis testing;
- Deletion of the guidelines for Aubagio (teriflunomide) that the beneficiary does not have a diagnosis of severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection;
- Deletion of the guidelines for Ocrevus (ocrelizumab) that the beneficiary does not have evidence of significant active infection;
- Deletion of the renewal guideline for Lemtrada that the beneficiary does not have signs of malignancy or autoimmune disorder;
- Deletion of the guidelines for Mayzent (siponimod) that the beneficiary has documentation of prescriber consultation with a cardiologist if recommended in the FDA-approved package labeling.

The revisions to the guidelines to determine medical necessity of prescriptions for Multiple Sclerosis Agents submitted for prior authorization, as recommended by the P&T

Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Multiple Sclerosis Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Multiple Sclerosis Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 ER), Aubagio (teriflunomide), Gilenya (fingolimod), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate DR).

3. 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

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 the provider handbook pages in the SECTION II chapter related to Tysabri (natalizumab); **OR**

2. For Zeposia (ozanimod), see the provider handbook pages in the SECTION II chapter related to Zeposia (ozanimod); **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 ER), 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 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 medical 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 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 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 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 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 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 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. 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 3 months.
    b. Renewal requests will be approved for up to 6 months.

2. For Lemtrada (alemtuzumab):

    a. Requests for an initial treatment course will be approved for up to 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.

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.
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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.