pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 12, 2020	January 5, 2021	*See below

SUBJECT

Prior Authorization of Multiple Sclerosis Agents – Pharmacy Services

BY

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Office of Medical Assistance Programs

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 managed care organization.

*01-20-36	09-20-35	27-20-31	33-20-32
02-20-29	11-20-29	30-20-28	
03-20-29	14-20-30	31-20-36	
08-20-39	24-20-29	32-20-28	

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.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical 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 August 12, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Multiple Sclerosis Agents:

- Revision of the guidelines for a non-preferred Multiple Sclerosis Agent that the beneficiary was prescribed in the past 90 days to account for agents in this class with a dosing interval that exceeds 90 days;
- Addition of a guideline for Zeposia (ozanimod) that the beneficiary has documented positive antibodies to varicella zoster virus (VZV), documentation of vaccination for VZV, or a healthcare professional confirmed history of chickenpox; and
- Addition of a guideline for renewals of requests for prior authorization of Multiple Sclerosis Agents to assess the beneficiary's response to therapy.

The revisions to the guidelines to determine medical necessity of Multiple Sclerosis Agents, 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), Aubagio (teriflunomide), Gilenya (fingolimod), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate).

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. 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 or activities of daily living; **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 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 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), 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 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 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) 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. The Department will limit authorizations consistent with FDA-approved package labeling.

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.