Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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).

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 Tysabri (natalizumab) policy; **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:

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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

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**

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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

    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.

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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. Gateway will limit authorizations consistent with FDA-approved package labeling.

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MULTIPLE SCLEROSIS AGENTS PRIOR AUTHORIZATION FORM *(form effective 01/05/2021)*

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Beneficiary's weight:	
Directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	
Has the beneficiary been receiving treatment with the requested medication?		☐Yes – *Submit documentation.* ☐No	

INITIAL requests

For a non-preferred Multiple Sclerosis Agent: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred drugs in this class that are approved or medically accepted for treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes ☐No *Submit documentation.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Has a relapsing form of MS *(specify)* → ☐clinically isolated syndrome ☐relapsing remitting disease ☐active secondary progressive disease
☐Has primary progressive MS

☐Request is for AMPYRA/DALFAMPRIDINE:
- ☐Has motor dysfunction on a continuous basis that impairs the ability to complete activities of daily living (ADLs) or instrumental ADLs
- ☐Has results of recent kidney function tests

☐Request is for AUBAGIO (teriflunomide):
- ☐Had a recent negative PPD test or blood test for tuberculosis
- ☐Does NOT have a severe immunodeficiency, bone marrow disease, or severe uncontrolled infection
- ☐Has results of recent liver function tests

☐Request is for GILENYA (fingolimod):
- ☐Has positive antibodies to VZV, was vaccinated for VZV, or has a history of healthcare professional-confirmed chickenpox
- ☐Did not receive a VZV vaccination in the previous 1 month
- ☐Has a comorbid cardiac condition – describe: _____

☐Request is for LEMTRADA (alemtuzumab): Dates of previous treatment course(s): _____
- ☐Had an inadequate response to 2 or more drugs indicated for the treatment of MS
- ☐Has positive antibodies to VZV, was vaccinated for VZV, or has a history of healthcare professional-confirmed chickenpox
- ☐Did not receive a VZV vaccination in the previous 6 weeks
- ☐Had a recent negative PPD test or blood test for tuberculosis

☐Request is for MAVENCLAD (cladribine): Dates of previous treatment course(s): _____
- ☐Had an inadequate response to or cannot tolerate 1 other drug indicated for the treatment of MS
- ☐Has results of a recent lymphocyte count

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☐ Has positive antibodies to VZV, was vaccinated for VZV, or has a history of healthcare professional-confirmed chickenpox

☐ Request is for MAYZENT (siponimod):
- ☐ Has positive antibodies to VZV, was vaccinated for VZV, or has a history of healthcare professional-confirmed chickenpox
- ☐ Has been tested for CYP2C9 variants to determine CYP2C9 genotype
- ☐ Has a comorbid cardiac condition – describe: _____
- ☐ Has any of the following:
  - ☐ history of cardiac arrest
  - ☐ cerebrovascular disease
  - ☐ uncontrolled hypertension
  - ☐ severe untreated sleep apnea
  - ☐ history of recurrent syncope
  - ☐ symptomatic bradycardia
- ☐ Is currently taking 1 or more medications that decrease heart rate (e.g., beta blockers, diltiazem, verapamil, ivabradine, digoxin)
- ☐ Prescriber consulted with a cardiologist regarding the appropriateness of treatment with Mayzent if recommended in package labeling

☐ Request is for OCREVUS (ocrelizumab):
- ☐ Does not have evidence of significant active infection

☐ Request is for ZEPOSIA (ozanimod):
- ☐ Has positive antibodies to VZV, was vaccinated for VZV, or has a history of healthcare professional-confirmed chickenpox

RENEWAL requests

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐ For Ampyra/dalfampridine, experienced an improvement in motor function since starting the requested medication

☐ For all MS drugs other than Ampyra/dalfampridine:
- ☐ Has a relapsing form of MS and experienced improvement or stabilization of the MS disease course since starting the requested medication
- ☐ Has primary progressive MS and continues to benefit from the requested medication

☐ Request is for AUBAGIO (teriflunomide):
- ☐ Does NOT have a severe immunodeficiency, bone marrow disease, or severe uncontrolled infection
- ☐ Has results of recent liver function tests

☐ Request is for GILENYA (fingolimod):
- ☐ Has a comorbid cardiac condition – describe: _____

☐ Request is for LEMTRADA (alemtuzumab): Dates of previous treatment course: _____
- ☐ Does not have signs of malignancy or autoimmune disorder

☐ Request is for MAVENCLAD (cladribine): Dates of previous treatment course(s): _____
- ☐ Has results of a recent lymphocyte count

☐ Request is for MAYZENT (siponimod):
- ☐ Has a comorbid cardiac condition – describe: _____
- ☐ Has any of the following:
  - ☐ history of cardiac arrest
  - ☐ cerebrovascular disease
  - ☐ uncontrolled hypertension
  - ☐ severe untreated sleep apnea
  - ☐ history of recurrent syncope
  - ☐ symptomatic bradycardia
- ☐ Is currently taking 1 or more medications that decrease heart rate (e.g., beta blockers, diltiazem, verapamil, ivabradine, digoxin)
- ☐ Prescriber consulted with a cardiologist regarding the appropriateness of treatment with Mayzent if recommended in package labeling

☐ Request is for OCREVUS (ocrelizumab):
- ☐ Does not have evidence of significant active infection

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: