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

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. For Zeposia (ozanimod), see the Zeposia (ozanimod) Policy; **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 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:

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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 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.

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

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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;

   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.

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MULTIPLE SCLEROSIS AGENTS PRIOR AUTHORIZATION FORM *(form effective 1/3/2022)*

☐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
- ☐Has a history of seizure

☐Request is for AUBAGIO (teriflunomide):
- ☐Has results of recent liver function tests

☐Request is for GILENYA (fingolimod):
- ☐Has a comorbid heart condition – describe: _____
- ☐Experienced any of the following in the past 6 months:
  - ☐Myocardial infarction
  - ☐Unstable angina
  - ☐Stroke
  - ☐Transient ischemic attack
  - ☐Decompensated heart failure
  - ☐Class III/IV heart failure

☐Request is for KESIMPTA (ofatumumab):
- ☐Does not have active hepatitis B virus infection

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

☐Request is for MAYZENT (siponimod):
- ☐Has been tested for CYP2C9 variants to determine CYP2C9 genotype
- ☐Has a comorbid heart condition – describe: _____
- ☐Experienced any of the following in the past 6 months:
  - ☐Myocardial infarction
  - ☐Unstable angina
  - ☐Stroke
  - ☐Transient ischemic attack
  - ☐Decompensated heart failure
  - ☐Class III/IV heart failure

☐Request is for OCREVUS (ocrelizumab):
- ☐Does not have active hepatitis B virus infection

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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
- ☐ Has a history of seizure

☐ 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):
- ☐ Has results of recent liver function tests

☐ Request is for GILENYA (fingolimod):
- ☐ Has a comorbid heart condition – describe: _____
- ☐ Experienced any of the following in the past 6 months:
  - ☐ Myocardial infarction
  - ☐ Unstable angina
  - ☐ Stroke
  - ☐ Transient ischemic attack
  - ☐ Decompensated heart failure
  - ☐ Class III/IV heart failure

☐ Request is for KESIMPTA (ofatumumab):
- ☐ Does not have active hepatitis B virus infection

☐ Request is for LEMTRADA (alemtuzumab): Dates of previous treatment course: _____

☐ 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 heart condition – describe: _____
- ☐ Experienced any of the following in the past 6 months:
  - ☐ Myocardial infarction
  - ☐ Unstable angina
  - ☐ Stroke
  - ☐ Transient ischemic attack
  - ☐ Decompensated heart failure
  - ☐ Class III/IV heart failure

☐ Request is for OCREVUS (ocrelizumab):
- ☐ Does not have active hepatitis B virus infection

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: