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Prior Authorization Criteria

Multiple Sclerosis Medications

All requests for Multiple Sclerosis medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Multiple Sclerosis Medications Prior Authorization Criteria:

Multiple Sclerosis Medications addressed in this policy include: Avonex (interferon beta-1a), Copaxone (glatiramer acetate), Gilenya (fingolimod), Tecfidera (dimethyl fumarate), and Ocrevus (Ocrelizumab)

Disclaimer: All requests for Multiple Sclerosis Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Multiple Sclerosis Medications all of the following criteria must be met:

- One of the following:
  - Member is 18 years of age or older
  - Request is for Gilenya and member is 10 years of age or older
- Must be prescribed by, or in consultation with, a neurologist or a physician that specializes in the treatment of MS
- The drug will not be given in combination with other disease modifying therapies approved for the treatment of MS
  - Gilenya and Tecfidera must not be given in combination with any antineoplastic, non-corticosteroid immunosuppressive or immune-modulating therapies used for the treatment of MS
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of relapsing forms of multiple sclerosis (e.g. relapsing-remitting, secondary-progressive, or progressive-relapsing multiple sclerosis) and the following criteria is met:

- For members initiating therapy for the first time, must provide documentation of one of the following:
  - One clinical relapse (e.g. functional disability, hospitalization, acute steroid therapy, etc.) during the prior year
  - Two relapses within the prior three years
  - A single clinical demyelinating event and 2 or more brain lesions characteristic of MS
  - For Tecfidera or Gilenya, a brain MRI scan demonstrating at least one gadolinium-enhancing (GD+) lesion within the past 6 months
- Coverage provided for situations in which there is functional status that can be preserved
  - Member must still either be able to walk at least a few steps **OR** alternatively must have some functional arm/hand use consistent with performing activities of daily living

- Requests for Ocrevus must also meet the following criteria:
    - Must provide documentation of Hepatitis B Virus (HBV) screening confirming negative HBsAg and anti-HB.
    - New starts must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to one of the following:
        - Gilenya
        - Glatiramer Acetate
        - Tecfidera
        - Avonex
- Requests for Gilenya must also meet the following criteria:
    - Member must have documentation of positive antibodies for varicella zoster virus (VZV) if there is no documentation of a healthcare professional confirmed history of chickenpox or documentation of a full course of vaccination against VZV
    - Member must have a recent ECG (within 6 months) with no evidence of heart block or bradycardia and has had an ophthalmologic exam of the macula prior to treatment initiation
    - Member does not have any contraindications to Gilenya including:
        - Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
        - History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
        - Baseline QTc interval ≥ 500 msec
        - Treatment with Class Ia or Class III anti-arrhythmic drugs
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Member continues to receive benefit from treatment by having the ability to walk at least a few steps or alternatively have some functional arm/hand use consistent with performing activities of daily living.
    - Must provide one of the following:
        - Documentation of clinical response defined as:
            - Member did not experience 1 or more relapses
            - Member does not have 2 or more unequivocally new MRI-detected lesions
        - Documentation of provider's clinical rationale for why alternative disease-modifying therapy (DMT) would be inappropriate for the member
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of primary progressive multiple sclerosis (MS) and the following criteria is met:

- Request must be for Ocrevus
- Must provide documentation of Hepatitis B Virus (HBV) screening confirming negative HBsAg and anti-HB.
- Must have one year of disease progression (retrospectively or prospectively determined), independent of clinical relapse, plus two of the following:

    - One or more hyperintense T2 lesions characteristics of MS in one or more of the periventricular, cortical, juxtacortical, or infratentorial areas
    - Two or more hyperintense T2 lesions in the spinal cord
    - Presence of cerebrospinal fluid-specific oligoclonal bands
- Coverage provided for situations in which there is functional status that can be preserved
    - Member must still either be able to walk at least a few steps **OR** alternatively must have some functional arm/hand use consistent with performing activities of daily living
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Documentation of clinical response defined as:
        - Member continues to receive benefit from treatment by having the ability to walk at least a few steps or alternatively have some functional arm/hand use consistent with performing activities of daily living.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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MULTIPLE SCLEROSIS MEDICATIONS PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Frequency:	Duration:	
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Relapsing Multiple Sclerosis ☐ Primary-Progressive Multiple Sclerosis ☐ Other: _____
ICD-10 Code: _____

Is there functional status that can be preserved? ☐ Yes ☐ No
☐ Member is able to walk at least a few steps
☐ Member has functional use of arm/hand consistent with performing activities of daily living

Will the medication be administered by a health care provider? ☐ Yes ☐ No

Please provide a medication list of any concurrent medications that the member will be taking.

For Relapsing Multiple Sclerosis:
Check any of the applicable statements:
☐ Member had at least one clinical relapse (e.g. functional disability, hospitalization, acute steroid therapy, etc.) during the prior year
☐ Member had two relapses within the prior two years
☐ Member had a single clinical demyelinating event and 2 or more brain lesions characteristic of MS

For Primary Progressive Multiple Sclerosis:
Check any of the applicable statements:
☐ Member has one year of disease progression (retrospectively or prospectively determined) independent of clinical relapse
☐ Member has one or more hyperintense T2 lesions characteristics of MS in one or more of the periventricular, cortical, juxtacortical, or infratentorial areas
☐ Member has two or more hyperintense T2 lesions in the spinal cord
☐ Cerebrospinal fluid-specific oligoclonal bands are present

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MULTIPLE SCLEROSIS MEDICATIONS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests) - continued

Requests for Ocrevus:
Has the member been screened for Hepatitis B Virus (HBV)? ☐ Yes ☐ No Date of screening: _____
Does the patient have active HBV? ☐ Yes ☐ No

Requests for Gilenya:
Does the member have documentation of receiving a full course of vaccination against varicella zoster virus? ☐ Yes ☐ No
If not, please provide documentation of positive antibodies for varicella zoster virus
Has the member had an ophthalmologic exam of the macula? ☐ Yes ☐ No
Has the member had a ECG within the last 6 months? ☐ Yes ☐ No
Please check any of the applicable statements:
☐ ECG has evidence of heart block or bradycardia ☐ Member has baseline QTc interval ≥ 500 msec
☐ Member has a history of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome without a pacemaker
☐ Member had a recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:_____

For Relapsing Multiple Sclerosis:
How many relapses has the member had in the last year? _____
How many unequivocally new MRI-detected lesions has the member had in the last year? _____

Prescribing Provider Signature	Date