

# Pharmacy

## PRIOR AUTHORIZATION FORM

For Prior Authorization, please fax toll-free (877) 974-4411, or local number (616) 942-8206

This form applies to:  Commercial Plan  Medicaid Plan  Medicare Plan

# Gilenya<sup>®</sup> (fingolimod)

**URGENT** (life threatening)

**Non-Urgent** (standard review)

A claim involving "urgent care" applies when the standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

### Member Information

Member Name:	Member No.:
DOB:	Gender:
Member's PCP:	

### Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

\_\_\_\_\_  
Provider Signature

\_\_\_\_\_  
Date

### PRODUCT INFORMATION

Gilenya<sup>®</sup> 0.5 mg capsule

**Dose:** 0.5mg once daily  
(Dosages exceeding 0.5mg once daily will be denied)

### THIS REQUEST IS FOR:

**New therapy** – complete SECTION A

**Continuation** therapy for a patient previously receiving Gilenya<sup>®</sup> with Priority Health or another health plan (manufacture starter packs are not considered continuation of therapy) – complete SECTION B

### NOTES:

1. Priority Health requires fingolimod (Gilenya<sup>®</sup>) to be obtained from our network preferred specialty pharmacy.
2. Authorization for Gilenya<sup>®</sup> will be approved at 12 months intervals.
3. Approval, when granted, will be for a 30 day supply per fill.

## SECTION A – NEW THERAPY

### PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Gilenya<sup>®</sup> (fingolimod) requires the following information to certify:

**A. Patient has a diagnosis of a relapsing form of multiple sclerosis with 1 clinical relapse in the previous year:**

Yes

No – Rationale for use: \_\_\_\_\_

**B. What is the patient's level of walking impairment?**

Ambulatory without aid, able to walk without aid or rest some 100 to 500 meters

Intermittent or unilateral constant assistance (cane, crutch, brace) required to walk about 100 meters with or without resting

Constant bilateral assistance (canes, crutches, braces) required to walk about 20 meters without resting.

Unable to walk beyond approximately 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day (request will be denied)

**C. Patient had a therapeutic trial and clinical failure with one preferred self-injectable MS therapy:**

Yes

Glatiramer (Copaxone). Dates of treatment: \_\_\_\_\_

Interferon Beta-1a (Rebif). Dates of treatment: \_\_\_\_\_

No - Rationale for use: \_\_\_\_\_

**D. The following laboratory values have been completed within 6 months prior to initiating Gilenya<sup>®</sup> therapy:**

CBC Date: \_\_\_\_\_

Liver transaminase Date: \_\_\_\_\_ Results: \_\_\_\_\_

Serum bilirubin Date: \_\_\_\_\_ Results: \_\_\_\_\_

**WARNING:** Gilenya<sup>®</sup> causes a dose-dependent reduction in peripheral lymphocyte count to 20-30% of baseline values because of reversible sequestration of lymphocytes in lymphoid tissues. BEFORE INITIATING TREATMENT with Gilenya<sup>®</sup>, a recent CBC (i.e. within 6 months) should be available.

**WARNING:** Gilenya<sup>®</sup> may increase liver transaminases. Recent liver enzyme results should be available before initiating treatment with Gilenya<sup>®</sup>. Assess liver enzymes if symptoms suggestive of hepatic injury develop. Discontinue Gilenya<sup>®</sup> if significant liver injury is confirmed.

**E. Check which of the follow apply to this patient:**

- Receiving concurrent therapy with antiarrhythmics  
(including beta-blockers, calcium channel blockers, Class Ia or III antiarrhythmics)

Patient has a history of:

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> 2nd degree or higher AV block | <input type="checkbox"/> sick sinus syndrome      | <input type="checkbox"/> prolonged QT interval   |
| <input type="checkbox"/> ischemic cardiac disease      | <input type="checkbox"/> congestive heart failure | <input type="checkbox"/> heart rate below 55 bpm |
| <input type="checkbox"/> irregular heart beat          |   |  |

If yes to any of the above items in section B, is there a baseline ECG available within the previous 6 months?

- Yes, date of ECG: \_\_\_\_\_
- No (request will be denied)

**WARNING:** Decrease in heart rate and/or atrioventricular conduction after first dose of Gilenya<sup>®</sup>: Observe all patients for signs and symptoms of bradycardia for 6 hours after first dose. Obtain baseline ECG before first dose if not recently available in those at higher risk of bradyarrhythmia. Patients receiving Class Ia or Class III antiarrhythmic drugs, beta blockers, calcium channel blockers, those with a low heart rate, history of syncope, sick sinus syndrome, 2nd degree or higher conduction block, ischemic heart disease, or congestive heart failure are at increased risk of developing bradycardia or heart blocks.

- F.  **Baseline ophthalmologic exam.** Date of exam: \_\_\_\_\_

**WARNING:** Macular edema can occur with or without visual symptoms. An ophthalmologic evaluation should be performed before starting Gilenya<sup>®</sup> and at 3-4 months after treatment initiation. Monitor visual acuity at baseline and during routine evaluations of patients. Patients with diabetes mellitus or a history of uveitis are at increased risk and should have regular ophthalmologic evaluations.

**G. If patient is a women, is she of childbearing potential?**

- No
- Yes – If yes, patient agrees to use a form of contraception to prevent pregnancy.

Gilenya<sup>®</sup> is associated with fetal risk. Women of childbearing potential should use effective contraception during and for two months after stopping Gilenya<sup>®</sup> treatment.

**H. Patient has documented immunity to varicella zoster virus (chicken pox):**

- No
- Date VZV vaccine given: \_\_\_\_\_ *Note: do not start Gilenya<sup>®</sup> therapy within 28 days of vaccination.*
- Patient will not be vaccinated. Rationale: \_\_\_\_\_
- Yes
- Patient was born before 1980
- Physician diagnosis of chicken pox
- Patient has been vaccinated with VZV. Date vaccine given: \_\_\_\_\_
- Positive VZV antibody. Date of lab confirmation: \_\_\_\_\_
- Other rationale for VZV immunity: \_\_\_\_\_

- I.  **Arrangements made for monitoring heart rate for up to 6 hours after administration of first dose.**

## SECTION B – CONTINUATION THERAPY

---

### PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for continuation of Gilenya<sup>®</sup> (fingolimod) requires the following information to certify:

---

**For continuing authorization of Gilenya, all of the following criteria must be met:**

- The patient is compliant in taking the medication as scheduled
- The patient tolerated the medication
- The patient did not experience any severe adverse reactions while taking the medication
- The patient has responded to treatment, as determined by the prescribing physician
- The patient does not have symptoms suggestive of hepatic dysfunction

## PRECERTIFICATION REQUIREMENTS

---

### PRIORITY HEALTH PRECERTIFICATION REQUIREMENTS

Authorization for Gilenya<sup>®</sup> (fingolimod) requires the following information to certify:

---

1. Patient must have one of the following diagnoses:
  - Relapsing/Remitting (RRMS)
  - Progressive Relapsing (PRMS)
2. Patient must have history of 1 clinical relapse within the 12 months prior to starting Gilenya<sup>®</sup>
3. Patient must currently be ambulatory, with minimal walking impairment, or use of cane, crutch, or brace.
4. Patient must have had a therapeutic trial and clinical failure with one of the following self-injectable therapies:
  - Copaxone (glatiramer), Avonex (Interferon Beta-1a), Rebif (Interferon Beta-1a), Betaseron (Interferon Beta-1b), or Extavia (Interferon Beta-1b)
5. The following laboratory values/tests/exams must be obtained and provided for review:
  - CBC
  - Liver transaminase
  - Serum bilirubin
  - ECG for patients using antiarrhythmics, or with history of 2nd degree or higher AV block, sick sinus syndrome, prolonged QT interval, ischemic cardiac disease, congestive heart failure, heart rate below 55bpm, or irregular heart beat
  - Ophthalmologic exam
  - Evidence of varicella zoster virus immunity
6. For women of childbearing potential, agreement to use forms of contraceptive to prevent pregnancies

**NOTE:** Fingolimod (Gilenya<sup>®</sup>) is **not indicated for and will not be approved** for non-relapsing forms of Multiple Sclerosis (e.g. primary progressive, secondary progressive) or Clinically Isolated Syndrome (CIS).

**\*\*\* All fields must be complete and legible for Prior Authorization Review\*\*\***

**Please fax this request to: (877)974-4411 toll free or (616)942-8206**

**YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**