PriorityHealth

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☐ **Commercial (Traditional)** ☐ **Commercial (Individual/Optimized)**
☒ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Gilenya® (fingolimod)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

☐ New request ☐ Continuation request

Drug product: ☐ Gilenya 0.5 mg capsule ☐ Gilenya 0.25 mg capsule*

Start date (or date of next dose): _____

Dose Requested: _____

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Must be 10 years of age or older
2. Have a diagnosis of relapsing-remitting multiple sclerosis (RRMS), secondary-progressive multiple sclerosis (SPMS) with relapses, or progressive-relapsing multiple sclerosis (PRMS), defined by the McDonald criteria
3. Gilenya is being prescribed by or in consultation with a board-certified neurologist or multiple sclerosis physician specialist with experience prescribing MS therapy
4. Expanded Disability Status Scale (EDSS) score between 0 and 5 (disability severe enough to impair full daily activities) **OR** documentation supporting the disability within this range
5. Patient will not be using a disease-modifying agent for MS at the same time as Gilenya
6. For patients age 18 and older:
    a. Documented inadequate response (at least 6 months of therapy) to non-interferon, glatiramer acetate (Copaxone), defined as meeting **TWO** of the following three criteria during treatment:
        - Increase in frequency (at least two clinical relapses within the past 12 months), severity and/or sequelae of relapses
        - Changes in MRI: continues to have CNS lesion progression as measured by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
        - Increase in disability progression: Sustained worsening of EDSS score, routine neurological observation, mobility, or ability to perform activities of daily living
7. For patients 10-17 years of age:
    a. Weight reported as >40kg for 0.5mg dose*

NOTE: "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to the first-line disease-modifying therapies (DMT's).

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 04/2019

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- ☐ Relapsing-remitting multiple sclerosis (RRMS)
- ☐ Secondary-progressive multiple sclerosis (SPMS)
- ☐ Progressive-relapsing multiple sclerosis (PRMS)
- ☐ *Other – the patient's condition is:* _____

Rationale for use: _____

B. Was Gilenya prescribed by or in consultation with a board-certified neurologist or multiple sclerosis physician specialist with experience prescribing MS therapy?

- ☐ Yes
- ☐ No

C. What is the patients Expanded Disability Status Scale (EDSS) score?

- ☐ 0-5 (disability severe enough to impair full daily activities) **OR** documentation supporting the disability within this range.
- ☐ *Other – Rationale for use:* _____

D. For patients age 18 and older:

a. Has the patient tried Copaxone (glatiramer acetate)?

- ☐ Yes. *Duration of use*:_____
- ☐ No. *Rationale:* _____

b. Which of the following describes the response to Copaxone (glatiramer acetate) (2 of the 3 must be met)?

- ☐ Increase in frequency (at least two clinical relapses within the past 12 months), severity and/or sequelae of relapses
- ☐ Changes in MRI: continues to have CNS lesion progression as measured by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
- ☐ Increase in disability progression: Sustained worsening of EDSS score, routine neurological observation, mobility, or ability to perform activities of daily living

NOTE: "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to the first-line disease-modifying therapies (DMT's)

E. For patients 10-17 years of age, what is their current weight? _____

F. Will the patient be treated with another disease-modifying agent for MS at the same time as Gilenya?

- ☐ Yes. *Rationale for use:* _____
- ☐ No

* Manufacturer reports that the 0.25mg dose, indicated for pediatric patients ≤ 40kg, will not be released on the market. Instead, it will be available through the manufacturer's Gilenya® Go Program®.

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