



## Prior Authorization Approval Criteria

### *Gilenya (fingolimod)*

<b>Generic name:</b>	fingolimod
<b>Brand name:</b>	Gilenya
<b>Medication class:</b>	Spinogosine 1-phosphate receptor modulator
<b>FDA-approved uses:</b>	Treatment of relapsing forms of multiple sclerosis
<b>Available dosage forms:</b>	0.5mg capsule
<b>Usual dose:</b>	0.5mg orally once daily
<b>Approximate monthly cost:</b> (based on AWP 2011)	\$4,742.40 per month
<b>Duration of therapy:</b>	Indefinite

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
  - Must be clinically diagnosed with relapsing remitting multiple sclerosis
  - Must be 18 years of age or older
  - Patients must be observed for 6 hours after the initial dose and all other doses where the patient has not received the medication for two weeks or longer
  - Failed/intolerant to Copaxone (glatiramer acetate)
  - Intolerant to both Avonex (IFN Beta-1a) and Betaseron (IFN Beta-1b)
- Or
- Failure with Avonex (IFN Beta-1a) or Betaseron (IFN Beta-1b)
    - Patient must have been compliant with treatment
    - Patient must meet at least one of the following conditions:
      - Two disabling relapses within a 12-month period
      - Secondary progression with an observable increase in disability over a six-month period
      - Loss of ability to walk for a period longer than six months

**Criteria for continuation of therapy:**

- Continued response – decrease in number of, or no relapses

**Caution:**

- Decrease in heart rate and/or atrioventricular conduction; rate returns to baseline within 1 month of treatment; patient must be observed for six hours after the initial dose
- Experience with concurrent beta-blocker therapy is limited
- Infections; number of circulating white blood cells is lowered
- Macular edema
- Reduction in FEV-1
- Not studied in patients with diabetes
- Consider varicella zoster virus vaccination in antibody negative patients

**Monitoring:**

- Recent ECG (within 6 months) before treatment initiation
- Recent CBC before treatment
- Ophthalmologic evaluation at baseline and 3-4 months after treatment
- Liver enzymes at baseline and during treatment
- Skin examination

**Contraindication:**

- None

**Not approved if:**

- Does not meet the above stated criteria.

**Special considerations:**

- Pregnancy category C
- Upon discontinuation, Gilenya is present in the blood for up to two months after last dose
- Detection of neutralizing antibodies to interferon beta is not currently accepted as an indicator that the patient has or will fail treatment with interferon beta.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

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

Adopted: 03/09/11