

## Pharmacy Policy Bulletin

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**Title:** Fingolimod (Gilenya®)

**Policy #:** Rx.01.36

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**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

### ▶ Intent:

Fingolimod (Gilenya®) is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

The use of fingolimod (Gilenya®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

### ▶ Description:

Fingolimod hydrochloride is metabolized to the active metabolite fingolimod phosphate, which is a sphingosine 1-receptor modulator. The mechanism of action of fingolimod (Gilenya®) in patients with multiple sclerosis is unknown, however, it may involve reduction of lymphocyte migration to the central nervous system.

### ▶ Policy:

**Fingolimod (Gilenya®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of a Relapsing form of Multiple Sclerosis
- Documentation of an inadequate response or a contraindication to **one** of the following:
  - Interferon beta-1a (Avonex®)
  - Interferon beta-1b (Betaseron®)
  - Glatiramer acetate Copaxone®)
  - Interferon beta-1b (Extavia®)
  - Interferon beta-1a (Rebif®)

### ▶ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

### ▶ References:

Chun J, Hartung HP. Mechanism of action of oral fingolimod (FTY720) in multiple sclerosis. *Clin Neuropharmacol*. 2010;33(2):91-101.


Facts & Comparisons. Gilenya®. [Facts & Comparisons Web site]. Available at: <http://online.factsandcomparisons.com> [via subscription only]. Accessed February 29, 2012.

Gilenya® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2010. Also available online at: <http://www.pharma.us.novartis.com/product/pi/pdf/gilenya.pdf>. Accessed February 29, 2012.

Micromedex. Gilenya®. [Micromedex web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed February 29, 2012.

National Multiple Sclerosis Society webpage. Available at: <http://www.nationalmssociety.org/>. Accessed February 29, 2012.

**Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Gilenya	fingolimod

**Cross References:**

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**Policy Version Number:** 1.00  
**P&T Approval Date:** January 12, 2012  
**Policy Effective Date:** April 01, 2012  
**Next Required Review Date:** January 12, 2013

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