



MEDICAL COVERAGE GUIDELINES  
SECTION: DRUGS

NEXT REVIEW DATE: 3RD QTR 2012

ORIGINAL EFFECTIVE DATE: 4/7/11  
LAST REVIEW DATE: 9/29/11  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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## Gilenya® (fingolimod) capsules 4-7-2011

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety. The guideline is not a guarantee of coverage.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational & thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available. The guideline in effect on the date of service will determine coverage.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

Gilenya is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. Gilenya is metabolized by sphingosine kinase to the active metabolite, fingolimod-phosphate. Fingolimod-phosphate is a sphingosine 1-phosphate receptor modulator, and binds with high affinity to sphingosine 1-phosphate receptors 1, 3, 4, and 5. Fingolimod-phosphate blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Gilenya exerts therapeutic effects in multiple sclerosis is unknown, but may involve reduction of lymphocyte migration into the central nervous system.

### Precertification:

Precertification\* for Gilenya is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail prescription benefit. Medications requiring precertification are identified on the following list located on the Internet at <http://www.azblue.com/pdfs/medications/pharmacy/QILList.pdf>:

*"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions"*

This list may also be requested by calling (602) 864-4273 or (800) 232-2345, ext. 4273.

Please refer to this list for other Gilenya prescription claim limitations where applicable.



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- \* Precertification will not be required for certain individuals who are already receiving Gilenya. Members having at least one BCBSAZ paid claim for Gilenya within the three months preceding the initial effective date of this guideline will not need to obtain precertification.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

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(cont.) **4-7-2011**

**Criteria:**

- FDA-approved dosage of Gilenya is considered **medically necessary** for the treatment of adult individuals (18 years of age and older) with a documented diagnosis of one of the following conditions:
  - Relapsing remitting multiple sclerosis (RRMS) characterized by clearly defined exacerbations of neurologic dysfunction followed by partial or complete recovery with no worsening or progression of disease
  - Secondary progressive multiple sclerosis (SPMS) that continues to relapse after some slight remission or plateau
  - Progressive relapsing multiple sclerosis (PRMS) that continues to relapse after some recovery from acute attacks
  
- And all of the following when applicable:
  - Documentation of **all of the following:**
    - Baseline (within 6 months) complete blood count (CBC) laboratory testing and evaluation, and as applicable during ongoing therapy
    - Baseline (within 6 months) liver transaminase and bilirubin laboratory testing and evaluation(s), and as applicable during ongoing therapy
    - Baseline (within 6 months prior to therapy) electrocardiogram (ECG) for individuals with an underlying higher risk of bradycardia and atrioventricular (AV) block.
    - Baseline ophthalmologic examination and an additional ophthalmologic examination 3-4 months after Gilenya therapy has been started
    - Varicella zoster virus (VZV) immunity
    - Women who are of child bearing potential are not pregnant and are confirmed to be using adequate birth control
    - Women who are breast feeding will discontinue breast feeding prior to therapy and will not resume breast feeding until Gilenya therapy is discontinued
    - Baseline pulmonary function testing and evaluation in individuals with clinically significant pulmonary disease

Gilenya:

- For all other indications not previously listed including Primary Progressive Multiple Sclerosis (PPMS);
- For intended use in those individuals with concomitant second degree or higher AV block, sick sinus syndrome, prolonged QT interval, ischemic cardiac disease, congestive heart failure, a sitting heart rate of less than 55 bpm;
- When concomitantly used with a class IA (e.g. quinidine, procainamide) or Class III (e.g.amiodarone, sotalol) antiarrhythmic drug or drugs;



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- When concomitantly used with an anti-neoplastic, immunosuppressive or immune modulating therapy for multiple sclerosis;
  - When intended for initiation of therapy in individuals with chronic infections;
  - When intended for initiation of therapy in individuals with an active infection;
  - When used concomitantly with live attenuated vaccines; and
  - When used in individuals with compromised respiratory function

is considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than established alternatives

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<b><u>History:</u></b>	<b><u>Date:</u></b>	<b><u>Activity:</u></b>
Pharmacy and Therapeutics review	3-22-11	Adopted guideline
Director Pharmacy Mgmt review	4-07-11	Development final

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**Criteria Revisions:**



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## **Gilenya (fingolimod) capsules Cont.**

### **Resources:**

Gilenya package insert review on September 2010

National Multiple Sclerosis Society: <http://www.nationalmssociety.org/about-multiple-sclerosis/relapsing-ms/index.aspx>

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