

Title: *fingolimod (Gilenya)*

Origination: 02/28/11	Revised: 11/11/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Fingolimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of members with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. The active metabolite, fingolimod-phosphate 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. This may involve a reduction of lymphocyte migration into the central nervous system (CNS).
- Fingolimod is the first oral medication for relapsing-remitting multiple sclerosis.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member less than 18 years of age, as safety and efficacy have not been established in children or adolescents.

Title: fingolimod (Gilenya)

Procedure:

- 1.0 Request for *initial therapy* of **multiple sclerosis (MS)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Provider must be a neurologist; **AND**
 - 1.2 Diagnosis of relapsing MS (RMS) or relapsing-remitting MS (RRMS); **AND**
 - 1.3 Member has a documented complete blood count (CBC) within the last six (6) months; **AND**
 - 1.4 Member has a documented liver transaminase and bilirubin level within the last six (6) months; **AND**
 - 1.5 Member currently using antiarrhythmics (including beta-blockers, calcium channel blockers, Class Ia and Class III antiarrhythmics) or with cardiac risk factors (2nd degree or higher AV blocks, sick sinus syndrome, prolonged QT interval, ischemic heart disease, or congestive heart failure, bradycardia less than 55 beats per minute) has a documented EKG (electrocardiogram) within the last six (6) months; **AND**
 - 1.6 Member has a documented ophthalmologic evaluation at time of initiation (within two (2) weeks); **AND**
 - 1.7 A documented history of chicken pox or administration of the varicella zoster vaccine (VZV) at least one month prior to starting Gilenya. If no history or administration of VZV, then titers should be drawn and if low VZV should be considered; **AND**
 - 1.8 Member has had an inadequate response (as demonstrated by continued disease activity measured clinically or by MRI) and/or intolerance to **all of the following** medications:
 - 1.8.1 Rebif; **AND**
 - 1.8.2 Copaxone;
 - 1.9 If the Member meets the above criteria, initial therapy may be approved for up to three (3) months at a dose of 0.5 mg daily.

Title: *fingolimod (Gilenya)*

Procedure, continued:

- 2.0 Request for *continuation of therapy* beyond the initial authorization period for **multiple sclerosis (MS)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying a reduction in the Member's signs and symptoms of MS (measured clinically or by MRI):
- 2.1 Documented adherence to fingolimod dosing regimen; **AND**
 - 2.2 Member is responding to therapy evidenced by no relapse; **AND**
 - 2.3 Documented absence of disability progression;
 - 2.4 If the Member meets the above criteria, continuation of therapy may be approved for up to one (1) year at a dose of 0.5 mg daily.

References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2008. Available at: <http://cp.gsm.com>.
2. Kappos, L *et al.* "A Placebo-Controlled Trial of Oral Fingolimod in Relapsing Multiple Sclerosis." *N Engl J Med* – Vol 362, Issue 5 (February 2010) - FREEDOMS Study Group pg. 387-401.
3. Gilenya [Package Insert] [Prescribing Information] Novartis Pharmaceuticals 2010.
4. Cohen, J *et al.* "Oral Fingolimod or intramuscular interferon for relapsing multiple sclerosis." *N Engl J Med* – Vol 362, Issue 5 (February 2010)- TRANSFORMS Study Group pg. 402-415.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.