

Complete Patient and Physician information (PLEASE PRINT)

STEP 1	Member Name:	Physician Name:
	Address:	Address:
	Member ID:	Phone #:
	Member DOB:	Fax #:
		Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment (all fields required):

STEP 2	Diagnosis	<input type="checkbox"/> Relapsing form of Multiple Sclerosis	<input type="checkbox"/> Other (Please state): _____ _____
	Clinical Consideration	Patient has previously been treated with an injectable disease-modifying agent (interferon, glatiramer, natalizumab, or mitoxantrone) Documentation required <input type="checkbox"/> Yes <input type="checkbox"/> No Which agent? _____	
		Indicate whether initial dose and first dose after a two week drug free period will be monitored for 6 hours with appropriate resuscitative equipment available <input type="checkbox"/> Yes <input type="checkbox"/> No	
		Is patient varicella antibody positive, or has the patient been vaccinated? First dose should be withheld for 1 month following immunization in antibody-negative patients <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Physician Specialty	<input type="checkbox"/> Neurologist	<input type="checkbox"/> Other (Please state): _____
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):		
	<i>*Please attach all relevant medical records and test results*</i> We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.		

STEP 3 **I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)**

 Prescriber Signature

 Date

STEP 4 **Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 11/11/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Gilenya (fingolimod)

CLASSIFICATION

- Immune Modulator

DESCRIPTION

- Fingolimod is indicated to treat relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. Fingolimod reduced the relapse rate in patients with relapsing remitting MS in a 2-year randomized controlled trial (RCT) that compared fingolimod to placebo (n=1272) and in a 1-year RCT that compared fingolimod with interferon beta-1a (n=912)
- Fingolimod hydrochloride is metabolized (via sphingosine kinase) to the active metabolite fingolimod phosphate, which is a sphingosine 1-receptor modulator. By binding to sphingosine 1-phosphate receptors 1, 3, 4, and 5, fingolimod phosphate prevents lymphocytes from exiting lymph nodes which reduces the lymphocyte count in the peripheral blood.
- The exact mechanism of action of fingolimod in patients with multiple sclerosis is unknown; however, it may work by reducing lymphocyte migration to the central nervous system
- Fingolimod reduced the relapse rate in patients with relapsing remitting MS in a 2-year randomized controlled trial (RCT) that compared fingolimod to placebo (n=1272) (Kappos et al, 2010) and in a 1-year RCT that compared fingolimod with interferon beta-1a (n=912) (Cohen et al, 2010).
- Fingolimod has a unique side-effect profile, lacks a documented long-term safety profile, and costs about \$1,000 more per month than the injectable disease-modifying therapies. Thus, it is deemed reasonable by RMHP to require failure of or intolerance to an injectable interferon product or Copaxone (glatiramer) before providing coverage for Gilenya (fingolimod).

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Tier 5

Commercial Formulary: Tier 4

Medicare Part D coverage: Tier 4

COVERAGE CRITERIA

Gilenya (fingolimod) meets the definition of **medical necessity** for the following:

- Relapsing forms of multiple sclerosis *after* disease progression or intolerance to another disease modifying drug
- Documentation required indicating patient has previously been treated with an injectable disease-modifying agent (interferon, glatiramer, natalizumab, or mitoxantrone)

Gilenya (fingolimod) is considered **experimental** for the following:

- Non-relapsing forms of multiple sclerosis (i.e. primary or secondary progressive)
- First line therapy of relapsing forms of multiple sclerosis (before a trial of interferon or glatiramer)

Required Provider Specialty:

- Approval is limited to Neurology

DOSAGE/ADMINISTRATION:

Adult Dosing:

- The recommended dose of fingolimod for the treatment of relapsing forms of multiple sclerosis is 0.5 mg orally once daily.
- Patients should be observed for 6 hours after the first dose for signs and symptoms of bradycardia
- Dose adjustment is not required for patients with renal impairment or with mild to moderate hepatic impairment
- Initiation of fingolimod should be withheld for 1 month following varicella zoster virus (VZV) vaccination in antibody-negative patients

PRECAUTIONS:

- Atrioventricular block may occur
- Bradycardia may occur; monitoring recommended
- Cardiac risk factors, including second degree or higher atrioventricular block, sick sinus syndrome, prolonged QT interval, ischemic cardiac disease, congestive heart failure, or patients with arrhythmias requiring antiarrhythmic drugs, slow or irregular heart beat; increased risk of atrioventricular block and bradycardia
- Concomitant use with antineoplastic, immunosuppressive or immune-modulating therapies, during or up to 2 months after last dose; may increase risk of immunosuppression
- Concomitant use with live attenuated vaccines should be avoided during and for 2 months after treatment; increased risk of infection
- Diabetes mellitus; increased risk of macular edema; monitoring recommended
- Hepatic enzyme elevations have been reported; monitoring recommended

- Hepatic impairment, severe; increased risk of adverse effects
- Hypertension may occur; monitoring recommended
- Infections may occur; possibly due to a reduction in peripheral lymphocyte counts; monitoring recommended
- Infection, acute or chronic; do not start fingolimod
- Macular edema may occur; monitoring recommended
- Respiratory function changes may occur, including a reduction in FEV1 and diffusion lung capacity for carbon monoxide (DLCO); monitoring recommended
- Uveitis, history of; increased risk of macular edema; monitoring recommended
- Varicella zoster virus, lack of immunity; vaccination is required

Billing/Coding information

CPT Coding:

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HCPCS Coding:

J8499	Prescription drug, Oral, Non-chemotherapeutic
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ICD-9 Diagnoses Codes That Support Medical Necessity:

340	Multiple Sclerosis
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COST

- AWP (January 2011): Gilenya 0.5mg capsule (1): \$158.08

COMMITTEE APPROVAL:

- January 26, 2011
- PA approved March 23, 2011

GUIDELINE UPDATE INFORMATION:

REFERENCES:

- DRUGDEX®, accessed 01/20/2011
- Product Information: GILENYA(R) oral capsules, fingolimod oral capsules. Novartis Pharmaceuticals Corporation, East Hanover, NJ, 2010.