

Gilenya (fingolimod) Policy Number: C10274-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
1/1/2012	2/12/2020	2/12/2021
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
J8499 (NOC)	RxPA	Q2 2020 20200422C10274-A

PRODUCTS AFFECTED:

Gilenya (fingolimod)

DRUG CLASS:

Sphingosine 1-Phosphate (S1P) Receptor Modulators

ROUTE OF ADMINISTRATION:

Oral

PLACE OF SERVICE:

Specialty Pharmacy

AVAILABLE DOSAGE FORMS:

Gilenya CAPS 0.25MG ,Gilenya CAPS 0.5MG- bottles of 30 capsules

Gilenya 0.25mg capsules are ONLY available through the Gilenya Go Program 1-800-598-1410

FDA-APPROVED USES:

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

COMPENDIAL APPROVED OFF-LABELED USES:

None

COVERAGE CRITERIA: INITIAL AUTHORIZATION**DIAGNOSIS:**

Multiple Sclerosis

REQUIRED MEDICAL INFORMATION:**A. RELAPSING FORM OF MULTIPLE SCLEROSIS:**

1. Documentation of a definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria (see Appendix), including: Relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS] with relapses, and progressive-relapsing multiple sclerosis [PRMS] or First clinical episode with MRI features consistent with multiple sclerosis
AND
2. Member is not currently being treated with a disease modifying agent (DMA) other than the requested agent
AND

3. Documentation member has completed a cardiac evaluation including a review of medications that could slow heart rate or atrioventricular (AV) conduction and an ECG will be done prior to the first dose and at the end of the first-dose observation period
AND
4. Documentation member has not had any of the following: recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
AND
5. Prescriber attestation of a complete blood cell count and liver enzyme laboratory testing was completed, reviewed, and deemed appropriate for Gilenya treatment by the prescriber
AND
6. Documentation of varicella zoster vaccination date or titer for antibodies or member has a labeled contraindication to the varicella zoster vaccines
AND
7. Documentation of ophthalmologic exam within the last 12 months to establish baseline status
AND
8. IF REQUEST IS FOR A NON-FORMULARY PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of therapy: 12 months

QUANTITY:

Maximum dosage (10 years or older OR more than 40 kg/88.2lbs): 0.5 mg orally once daily, maximum dosage for ages 10 AND up to 88.2lbs: 0.25 mg orally once daily

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board certified neurologist or a multiple sclerosis specialist. Please submit consultation notes if prescribed after consultation

AGE RESTRICTIONS:

For ages 10 AND up to 88.2lbs: 0.25 mg., If pt exceeds 88.2lbs they will be recommended for the 0.5mg regardless of age

CONTINUATION OF THERAPY:**A. RELAPSING FORM OF MULTIPLE SCLEROSIS:**

1. (a) Documentation of a stable number or decrease in acute attacks (relapses) within the last 6 months
OR
(b) Documentation of lack of progression or sustained disability
OR
(c) Recent (within last 6 months) MRI shows lack of development of new asymptomatic lesions
AND
2. Documentation member has been adherent to therapy at least 85% of the time as verified by Prescriber and member's medication fill history
AND
3. Member had not experienced any intolerable adverse effects or drug toxicity
AND
4. Prescriber attestation of updated ophthalmic exam (recommended 3-4 months after starting therapy) and liver function tests since original authorization demonstrating no adverse effects
AND

5. (a) Documentation member has not had a treatment lapse of greater than 14 days
OR
(b) If member has had a treatment lapse of greater than 14 days, first dose monitoring will be done again

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Gilenya (fingolimod) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:

Gilenya Safety Alert November 2018

The FDA has issued a safety alert warning that when Gilenya (fingolimod) is stopped, multiple sclerosis (MS) can become much worse than before Gilenya was started or while it was being taken, and can result in permanent disability. Because of this, a new warning regarding this risk has been added to the prescribing information and Medication Guide of Gilenya.

Health care professionals should inform patients about the potential risk of severe increase in disability after stopping Gilenya. When Gilenya is stopped, patients should be carefully observed for evidence of their MS worsening. Patients should seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped.

BACKGROUND:

Gilenya, a sphingosine 1-phosphate receptor modulator, 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 recommended dose of Gilenya is 0.5 mg orally once daily. The initiation of Gilenya leads to decreases in heart rate. After the first dose of Gilenya, the heart rate decreases are noted within an hour and generally are greatest at 6 hours, although the effects can be observed 24 hours after the first dose in some patients. The first dose of Gilenya should be given in a setting with resources to appropriately manage symptomatic bradycardia

APPENDIX:

Summary of 2017 McDonald Criteria for the Diagnosis of MS

CLINICAL PRESENTATION	ADDITIONAL CRITERIA TO MAKE MS DIAGNOSIS
...in a person who has experienced a typical attack/CIS at onset	
<ul style="list-style-type: none"> • 2 or more attacks and clinical evidence of 2 or more lesions; OR • 2 or more attacks and clinical evidence of 1 lesion with clear historical evidence of prior attack involving lesion in different location 	None. DIS and DIT have been met.
<ul style="list-style-type: none"> • 2 or more attacks and clinical evidence of 1 lesion 	DIS shown by <u>one</u> of these criteria: <ul style="list-style-type: none"> - additional clinical attack implicating different CNS site - 1 or more MS-typical T2 lesions in 2 or more areas of CNS: periventricular, cortical, juxtacortical, infratentorial or spinal cord
<ul style="list-style-type: none"> • 1 attack and clinical evidence of 2 or more lesions 	DIT shown by <u>one</u> of these criteria: <ul style="list-style-type: none"> - Additional clinical attack - Simultaneous presence of both enhancing and non-enhancing MS-typical MRI lesions, or new T2 or enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan) - CSF oligoclonal bands
<ul style="list-style-type: none"> • 1 attack and clinical evidence of 1 lesion 	DIS shown by <u>one</u> of these criteria: <ul style="list-style-type: none"> - Additional attack implicating different CNS site - 1 or more MS-typical T2 lesions in 2 or more areas of CNS: periventricular, cortical, juxtacortical, infratentorial or spinal cord AND DIT shown by <u>one</u> of these criteria: <ul style="list-style-type: none"> - additional clinical attack - Simultaneous presence of both enhancing and non-enhancing MS-typical MRI lesions, or new T2 or enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan) - CSF oligoclonal bands
...in a person who has steady progression of disease since onset	
1 year of disease progression (retrospective or prospective)	DIS shown by at least <u>two</u> of these criteria: <ul style="list-style-type: none"> - 1 or more MS-typical T2 lesions (periventricular, cortical, juxtacortical or infratentorial) - 2 or more T2 spinal cord lesions - CSF oligoclonal bands

DIT = Dissemination in time CNS = central nervous system CSF = cerebrospinal fluid
 DIS = Dissemination in space T2 lesion = hyperintense lesion on T2-weighted MRI

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Gilenya (fingolimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation;

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2. Berger JR, Cree BA, Greenberg B, et al. Progressive multifocal leukoencephalopathy after fingolimod treatment. *Neurology*. 2018;90(20):e1815-e1821. doi: 10.1212/WNL.0000000000005529.
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.
4. Thompson, A., Banwell, B. et al. (2018). Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *The Lancet Neurology*, 17(2), pp.162-173.