Gilenya (fingolimod)
Policy Number: C10274-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
1/1/2012	3/1/2019	3/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
NA	PA	Q2

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. The member is not currently being treated with a disease modifying agent (DMA) other than the requested agent
   AND
3. Documentation patient 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. Documentation 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

GENDER:
Male and female

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. Documentation of updated ophthalmic exam (recommended 3-4 months after starting therapy) and live 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

REFERENCES:

1. Gilenya (fingolimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019.
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., Barkhof, F., Carroll, W., Coetzee, T., Comi, G., Correale, J., Fazekas, F., Filippi, M., Freedman, M., Fujihara, K., Galetta, S., Hartung, H., Kappos, L., Lublin, F., Marrie, R., Miller, A., Miller, D., Montalban, X., Mowry, E., Sorensen, P., Tintoré, M., Traboulsee, A., Trojano, M., Uitdehaag, B., Vukusic, S., Waubant, E., Weinshenker, B.,

Reingold, S. and Cohen, J. (2018). Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. The Lancet Neurology, 17(2), pp.162-173.