CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Gilenya (fingolimod)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 30 caps per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Gilenya (fingolimod) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS

For **initial** authorization:

1. Member must be 10 years of age or older and chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. A complete blood count (CBC) must be obtained before treatment start; AND
4. The risk of progressive multifocal leukoencephalopathy (PML) was discussed with member before starting Gilenya; AND
5. Member must **not** have experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure within the last 6 months; AND
6. Member must **not** have history or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker; AND
7. Member must have documentation in chart notes that baseline QTc interval is not greater than 500 msec; AND
8. Member must **not** currently be receiving treatment with Class Ia or Class III anti-arrhythmic drugs.
9. **Dosage allowed:** 0.5 mg orally once daily.

Note: Examine the fundus before starting therapy and three to four months after to evaluate for macular edema**.**

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Gilenya (fingolimod) not medically necessary for the treatment of the following disease states based on a lack of robust clinical

controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Gilenya created. Not covered diagnosis added. Contraindications added in criteria. Baseline QTc interval required.
12/06/2017	Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer required.
09/13/2018	Age coverage expanded into pediatric population. CBC baseline and suggested discussion with member about PML risks prior to treatment were added to criteria.

References:

1. Gilenya [package insert]. East Hanover, NJ; Novartis Pharmaecuticals, Inc., May 2018.
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3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Annals of Neurology. 2011;69(2):292-302. doi:10.1002/ana.22366.
5. ClinicalTrials.gov. Identifier: NCT 01892722. Safety and Efficacy of Fingolimod in Pediatric Patients With Multiple Sclerosis. Available at: https://clinicaltrials.gov/ct2/show/NCT01892722?term=NCT+01892722&rank=1.
6. Kappos L, et al. A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis. N Engl J Med. 2010 Feb 4;362(5):387-401.
7. Cohen JA, et al. Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis. N Engl J Med. 2010 Feb 4;362(5):402-15.
8. Fox EJ, et al. New treatments and treatment goals for patients with relapsing-remitting multiple sclerosis. Curr Opin Neurol. 2012 Feb;25 Suppl:S11-9.
9. Calabresi PA, et al. Safety and efficacy of fingolimod in patients with relapsing-remitting multiple sclerosis (FREEDOMS II): a double-blind, randomised, placebo-controlled, phase 3 trial. Lancet Neurol. 2014 Jun;13 (6):545-56.

Effective date: 10/01/2018
Revised date: 09/13/2018