



## Commercial/Healthcare Exchange PA Criteria Effective: January 1, 2019

**Prior Authorization:** Gilenya

**Products Affected:** Gilenya (fingolimod) oral capsule

**Medication Description:** Fingolimod is metabolized by sphingosine kinase to the active metabolite, fingolimod-phosphate. Fingolimod-phosphate is a sphingosine 1-phosphate receptor modulator, and 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. The mechanism by which fingolimod exerts therapeutic effects in multiple sclerosis is unknown, but may involve reduction of lymphocyte migration into the central nervous system.

**Covered Uses:** Gilenya is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

**Exclusion Criteria:**

Gilenya is contraindicated in patients who have:

1. in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure.
2. a history or presence of Mobitz Type II second-degree or third-degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker.
3. a baseline QTc interval  $\geq 500$  msec.
4. cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs

**Required Medical Information:** Diagnosis

**Age Restrictions:** 10 years of age and older

**Prescriber Restrictions:** Prescribed by, or in consultation with, a neurologist or a physician that specializes in MS.

**Coverage Duration:** 3 years

**Other Criteria:**

- A. Patient has a diagnosis of any of the following relapsing forms of Multiple Sclerosis:
  - a. Progressive-relapsing multiple sclerosis (PRMS); OR
  - b. Relapsing-remitting multiple sclerosis (RRMS); OR
  - c. Secondary progressive multiple sclerosis (SPMS) with documented relapses; OR
  - d. Clinically isolated syndrome

**References:**

Last Res.6.2.2020



Confidential Information

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1. GILENYA(R) oral capsules, fingolimod oral capsules. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2018.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Update to 3 years	07/01/2019
3	Update	Adopted EH policy and template;  Removed from CCI MS Drug Policy  Updated Indication to include CIS	All	6/2/2020