



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

Prior Authorization: Gilenya

Products Affected: Gilenya (fingolimod) oral capsule, Fingolimod oral capsules, Tascenso ODT

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

Tascenso ODT: pediatric patients 10 years of age and older and weighing less than or equal to 40 kg

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

Last Res. February 2023



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References:

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

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
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
4	Update	Added Fingolimod oral capsules to Products Affected	Products Affected	10/31/2022
5	Update	Added Tascenso ODT to Products Affected and Age Restrictions	Products Affected, Age Restrictions	2/1/2023

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