CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Fingolimod (Gilenya, Tascenso ODT)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Gilenya was initially approved by the FDA in 2010. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS). It was the first oral drug approved for MS and later became the first drug approved for MS in the pediatric population. MS is a chronic autoimmune disease of the central nervous system that disrupts communication in the brain and between the brain and body. Gilenya was the first sphingosine-1-phosphate (S1P) receptor modulator. It requires all patients to be monitored for 6 hours after the first dose is given due to the potential for bradycardia. Tascenso ODT is a 505 (b)(2) product of Gilenya.

Fingolimod will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 10 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of a relapsing form of MS (i.e., clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease); AND
4. The following baseline assessments have been completed (or are scheduled):
   a) A complete blood count (CBC)
   b) An ophthalmic evaluation
   c) Baseline QTc interval is less than 500 msec
   d) Baseline liver function tests; AND
5. The risk of progressive multifocal leukoencephalopathy (PML) has been discussed; AND
6. Member has not experienced any of the following in the past 6 months: Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
7. Member does not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker; AND
8. Fingolimod will not be used concomitantly with any other disease modifying drugs for MS; AND
9. If the request is for Tascenso ODT, member must have trial and failure of Gilenya or inability to swallow capsules.
10. **Dosage allowed/Quantity limit:**
    Adults and pediatrics 10 years of age and older weighing more than 40 kg: 0.5 mg once daily
    Pediatrics 10 years of age and older weighing less than or equal to 40 kg: 0.25 mg once daily
    QL: 30 capsules/tablets per 30 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as fewer relapses or no new or enlarging lesions on MRI.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers fingolimod not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
10/12/2021	Transferred to new template. General changes to language for consistency with related drugs. Updated references. Removed CIS from exclusion list and added to criteria. Moved ophthalmic note into the criteria. Added baseline LFT's. Added note regarding concomitant use. Added pediatric dosing. Added renewal criteria. Removed anti-arrhythmic exclusion, could be ok if they have cardiac consult.
11/09/2022	Renamed policy as generic name and added Tascenso ODT (505b2) to policy. Added reference for pediatric MS. Added QL.
04/19/2023	Removed restriction for Tascenso only being for those under 40 kg.

References:

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