Gilenya

Description

Gilenya (fingolimod)

Background
Gilenya (fingolimod) is a sphingosine-1-phosphate-receptor (S1PR) modulator that binds to receptors in the body that block progression of lymphocytes (white blood cells) into the blood and may reduce the movement of lymphocytes into the central nervous system. Although the exact mechanism of action in Multiple Sclerosis (MS) is unknown, it is thought that through this inhibition, lymphocytes are unable to destroy the myelin sheath which leads to lesions that are characteristic of MS and reducing the severity of MS (1).

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 (1).

Regulatory Status
FDA approved indication: Gilenya is a sphingosine-1-phosphate receptor indicated for the treatment of patients 10 years of age and older with relapsing forms of multiple sclerosis (1).

Patients with some pre-existing conditions (e.g., ischemic heart disease, history of myocardial infarction, congestive heart failure, history of cardiac arrest, cerebrovascular disease, history of symptomatic bradycardia, history of recurrent syncope, severe untreated sleep apnea, AV block, sino-atrial heart block) may poorly tolerate the Gilenya-induced bradycardia, or experience serious rhythm disturbances after the first dose of Gilenya. Prior to treatment with Gilenya, patients should have a cardiac evaluation by a physician appropriately trained to
conduct such evaluation, and, if treated with Gilenya after the first dose patients should be monitored for 6 hours for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement and overnight with continuous ECG in a medical facility (1).

Gilenya is contraindicated in patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, baseline QT interval ≥500 ms, or Class III/IV heart failure (1).

Gilenya is contraindicated in patients with Mobitz Type II 2nd degree or 3rd degree AV block, a prolonged QTc interval or at risk for QT prolongation, or concomitant use of Class Ia or Class III anti-arrhythmic drugs (1).

If Gilenya therapy is discontinued for more than 14 days, after the first month of treatment, the effects on heart rate and AV conduction may recur on reintroduction of Gilenya treatment and the same precautions (first dose monitoring) as for initial dosing should apply. Within the first 2 weeks of treatment, first dose procedures are recommended after interruption of one day or more, during week 3 and 4 of treatment first dose procedures are recommended after treatment interruption of more than 7 days (1).

Before initiating treatment with Gilenya, a recent CBC should be available due to Gilenya increasing the risk of infection. Macular edema occurred in 0.4% of patients receiving Gilenya therefore an ophthalmologic evaluation should be performed at baseline and 3 to 4 months after initiation of treatment; patients with diabetes with a history of uveitis are at increased risk. Elevations of liver enzymes may occur in patients and a recent transaminase and bilirubin level should be done before initiation of Gilenya therapy. Gilenya may cause a decrease in pulmonary function tests and spirometry and diffusion lung capacity for carbon monoxide should be obtained with clinically indicated. Gilenya should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (1).

Gilenya has not been administered concomitantly with antineoplastic, immunosuppressive or immune modulating therapies used for treatment of MS. Concomitant use of Gilenya with any of these therapies would be expected to increase the risk of immunosuppression (1).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated (2).

Gilenya has been approved in the US with a Risk Evaluation and Mitigation Strategy (REMS) to inform patients and healthcare providers on the safe use and serious risks of Gilenya in treating
relapsing forms of MS. The approved REMS includes a medication guide for patients, and a letter and safety information guide for healthcare providers (1).

Safety and effectiveness in pediatric patients with MS below the age of 10 have not been established (1).

Related policies
Acthar Gel, Ampyra, Aubagio, Lemtrada, Mavenclad, Mayzent, MS Injectables, Ocrevus, Tecfidera, Tysabri

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gilenya may be considered **medically necessary** in patients 10 years of age or older that have a documented diagnosis of a relapsing form of Multiple Sclerosis (MS) and if the conditions indicated below are met.

Gilenya may be considered **investigational** in patients less than 10 years of age and for all other indications.

Prior-Approval Requirements

**Age**
10 years of age or older

**Diagnosis**

Patient must have the following:

- Relapsing form of Multiple Sclerosis (MS)

**AND ALL** of the following:
1. Member must be observed for 6 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurements and an ECG prior to dosing and at the end of the observation period
2. NO history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure

3. NO history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker

4. NO concurrent use with other MS disease modifying agents

5. NOT given concurrently with live vaccines

Prior – Approval Renewal Requirements

Age  10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS)

AND ALL of the following:

1. NO history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.

2. NO history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker

3. NO concurrent use with other MS disease modifying agents

4. NOT given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity
**Strength** | **Quantity Limit per 90 days**
---|---
0.25 mg capsule* | 90 capsules per 90 days
0.5 mg capsule | 

*This strength is included in this policy but is not available in the market as of yet

**Duration**
12 months

**Prior – Approval Renewal Limits**
Same as above

**Rationale**

**Summary**
Gilenya is indicated in the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. The first dose of Gilenya should be administered in a setting in which resources to appropriately observe and manage symptomatic bradycardia are available. Gilenya is contraindicated in patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure or Class III/IV heart failure. Gilenya is also contraindicated in patients with Mobitz Type II 2nd degree or 3rd degree AV block. Safety and effectiveness in pediatric patients with MS below the age of 10 have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Gilenya while maintaining optimal therapeutic outcomes.

**References**

**Policy History**

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>April 2012</td>
<td>New PA policy</td>
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March 2013          Annual editorial review and reference update
                   Addition to criteria that the patient must not have a history or presence of
                   Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome;
                   unless patient has a pacemaker. Added no concurrent therapy with Class
                   Ia or Class III anti-arrhythmic drugs.

September 2013     Annual editorial review and reference update

December 2014      Annual editorial review and reference update. Removal of “not being
                   treated with Class Ia and Class III anti-arrhythmics” and examples from
                   criteria of other MS disease modifying agents

February 2015       Change in PA Allowance from 84 caps per 84 days to accommodate new
                   packaging of 30 count

March 2015          Annual editorial review and reference update

                   Policy code changed from 5.07.08 to 5.60.08

December 2016      Annual editorial review and reference update
                   Addition of not given concurrently with live vaccines

March 2017          Annual review

June 2017           Annual review

June 2018           Decrease in age to 10 years of age and older.
                   Addition of 0.25 mg strength

September 2018     Annual review

September 2019     Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on
September 13, 2019 and is effective on October 1, 2019.