Clinical Policy: Fingolimod (Gilenya)

Reference Number: CP.PHAR.251
Effective Date: 08/16 Revision Log
Last Review Date: 08/17

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for fingolimod (Gilenya®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Gilenya is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of relapsing-remitting multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Member will not use other disease modifying therapies for MS concurrently;
5. At the time of request, member does not have any of the following contraindications:
   a. Any of the following in the last 6 months: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure;
   b. History of Mobitz Type II 2nd degree or 3rd degree atrioventricular block or sick sinus syndrome, unless member has a pacemaker;
   c. Baseline QTc interval ≥ 500 msec;
   d. Treatment with Class Ia or Class III anti-arrhythmic drugs (see Appendix B);
6. Dose does not exceed 0.5 mg/day (1 capsule/day).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions);
3. Member is not using other disease modifying therapies for MS concurrently;
4. If request is for a dose increase, new dose does not exceed 0.5 mg/day (1 capsule/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:
Fingolimod is a sphingosine 1-phosphate receptor modulator. It 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 MS is unknown, but may involve reduction of lymphocyte migration into the central nervous system.

Formulations:
Gilenya is available as 0.5 mg hard capsules with a white opaque body and bright yellow cap imprinted with "FTY 0.5 mg" on the cap and 2 radial bands imprinted on the capsule body with yellow ink.

FDA Approved Indication(s):
Gilenya is a sphingosine 1-phosphate receptor modulator/oral capsule indicated for:
- Treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Appendices

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Class Ia or Class III Anti-arrhythmic Drugs

Class Ia	*Class III*	
• Disopyramide	• Amiodarone	• Sotalol
• Procainamide	• Dofetilide	• Dronedarone
• Quinidine	• Ibutilide	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.18 MS Treatments. Criteria: added max dosing, clarified monotherapy restriction, removed re-authorization requirement for documented adherence, updated contraindications and reasons to discontinue, modified efficacy criteria from "No increase in neurologic dysfunction/disability as a result of relapses or progressive disease, including a change in diagnostic status from RRMS to SPMS" to "Responding positively to therapy". Removed requirement for MRI confirmation of MS.	06/16	08/16

Reviews, Revisions, and Approvals	Date	Approval Date
Changed renewal approval duration to 12 months		
Added age requirement. Removed MRI requirement.Removed the following contraindications: active infection and hypersensitivity.Removed reasons to discontinue.	07/17	08/17

References

1. Gilenya Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation; February 2016. Available at http://www.gilenya.com. Accessed June 14, 2017.
2. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. July 2016. Accessed June 13, 2017.
3. Olek MJ. Disease-modifying treatment of relapsing-remitting multiple sclerosis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed June 13, 2017.
4. Olek MJ. Diagnosis of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed June 13, 2017.
5. Vaughn Williams EM. Classifying antiarrhythmic actions: by facts or speculation. J Clin Pharmacol. 1992; 32(11): 964-977.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.