Clinical Policy: Fingolimod (Gilenya)

Reference Number: PA.CP.PHAR.251
Effective Date: 01/18
Last Review Date: 08/17

Revision Log

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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Gilenya is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of relapsing form of 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 PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.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

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.