Clinical Policy: Fingolimod (Gilenya)

Reference Number: PA.CP.PHAR.251
Effective Date: 01/18
Last Review Date: 04/19

Revision Log

Description
Fingolimod (Gilenya®) is a sphingosine 1-phosphate receptor modulator.

FDA Approved Indication(s)
Gilenya is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older

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 ≥ 10 years;
4. Member will not use other disease modifying therapies for MS concurrently (*see Appendix D*);
5. At the time of request, member does not have baseline QTc interval ≥ 500 msec;
6. Dose does not exceed 0.5 mg (1 capsule) per day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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;
3. Member is not using other disease modifying therapies for MS concurrently (*see Appendix D*);
4. If request is for a dose increase, new dose does not exceed 0.5 mg (1 capsule) per 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.PMN.53**.**

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

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
  - History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
  - Baseline QTc interval ≥ 500 msec
  - Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
  - Hypersensitivity to fingolimod or its excipients
- Boxed warning(s): none reported

Appendix D: General Information
- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzmab (Ocrevus™).

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed the following contraindications: recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure; history of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker; references reviewed and updated.	01.05.18	
2Q 2019 annual review: removed requirement for no concurrent use of Class Ia or III anti-arrhythmic drugs based on updated contraindication in FDA label; references reviewed and updated.	04.17.19	

References
1. Gilenya Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019. Available at http://www.gilenya.com. Accessed February 4, 2019.
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. March 2017. Accessed February 4, 2019.

3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.