Clinical Policy Title:	fingolimod
Policy Number:	RxA.145
Drug(s) Applied:	Gilenya®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Fingolimod (Gilenya®) is a sphingosine 1-phosphate receptor modulator and is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
fingolimod (Gilenya®)	Relapsing MS	Adults and pediatric patients 10 years of age and older weighing greater than 40 kg: 0.5 mg PO once daily (with or without food) Pediatric patients 10 years of age and older weighing 40 kg or less: 0.25 mg PO once daily (with or without food)	0.5 mg/day

Dosage Forms

- Capsule: 0.25 mg, 0.5 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of one of the following (a, b, or c):
   a. Clinically isolated syndrome;
   b. Relapsing-remitting MS;
   c. Secondary progressive MS;
2. Prescribed by or in consultation with a neurologist;
3. Member is 10 years of age or older;
4. Trial and failure of at least two (2) preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Glatopa,

Firdapse, Kesimpta, Ocrevus, Plegridy, Ruzurgi, or Zeposia;
5. Fingolimod is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
6. At the time of request, member does not have baseline QTc interval 500 msec or greater;
7. Dose does not exceed one of the following (a or b):
   a. Body weight is greater than 40 kg: 0.5 mg (1 capsule) per day;
   b. Body weight 40 kg or less: 0.25 mg (1 capsule) per day

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Fingolimod is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Body weight is greater than 40 kg: 0.5 mg (1 capsule) per day;
   b. Body weight 40 kg or less: 0.25 mg (1 capsule) per day

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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 of 500 msec or greater
  - 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:
  - Infusion therapies:
    - alemtuzumab (Lemtrada®)
    - mitoxantrone (Novantrone®)
    - natalizumab (Tysabri®)
    - ocrelizumab (Ocrevus™)
    - rituximab (Rituxan®)
  - Oral therapies:
    - cladribine (Mavenclad®)
    - dimethyl fumarate (Tecfidera®)
    - diroximel fumarate (Vumerity®)
    - fingolimod (Gilenya®)
    - ozanimod (Zeposia®)
    - siponimod (Mayzent®)
    - teriflunomide (Aubagio®)
  - Injection therapies:
    - glatiramer acetate (Copaxone®, Glatopa®),
    - interferon beta-1a (Avonex®, Rebif®)
    - interferon beta-1b (Betaseron®, Extavia®)
    - ofatumumab (Kesimpta®)
    - peginterferon beta-1a (Plegridy®)
- Limitation of Use: Fingolimod is not recommended to use in pregnancy because of the risk of fetal harm. Advise to avoid becoming pregnant while taking fingolimod or within the two (2) months after stopping the medication.

References

1. Gilenya® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019. Available at http://www.Gilenya®.com. Accessed February 18, 2021.
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. June 2019 . Accessed February 18, 2021.
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. Accessed February 18, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 2. Updated dose does not exceed based on body weight 3. Added limitation of use (pregnancy) under appendix D 4. Made commercial and Medicaid approval duration the same (removed length of benefit from commercial) 5. References reviewed and updated.	06/15/2020	09/14/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Criteria for approval updated. 3. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 4. References were reviewed and updated.	04/26/2021	06/10/2021