Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Gilenya® (Fingolimod)***
DEPARTMENT: **Clinical Pharmacy Service – Utilization Management**
ORIGINAL DATE: ***October 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *September 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Gilenya® (fingolimod).

Gilenya® (fingolimod) is indicated for 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.

DEFINITIONS

Class Ia Antiarrhythmic Medications – slow conduction velocity and prolong action potential duration; examples include disopyramide, procainamide, and quinidine

Class III Antiarrhythmic Medications – prolong the action potential duration but have no effect on conduction; examples include amiodarone, dofetilide, ibutilide, sotalol, n-acetyl procainamide (NAPA), and dronedarone

QT interval – a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. A prolonged QT interval is a risk factor for ventricular tachyarrhythmia and sudden death.

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POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Gilenya® (fingolimod), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist
- Must have a diagnosis of relapsing form of multiple sclerosis
- Must be age 10 years or older
- Must be observed for 6 hours for signs and symptoms of bradycardia with initial dose
- Must have recent (within 6 months) Complete Blood Count (CBC)
- Must have recent (within 6 months) transaminase and bilirubin levels
- Must have recent (within 1 month) electrocardiogram (ECG)
- Must have a baseline QTc interval ≤ 500ms
- Must have no evidence of active infection
- Must demonstrate immunity to varicella zoster virus (VZV) by VZV antibody serology
    - Demonstrated immunity is NOT required for patients who have been vaccinated against VZV. Chart documentation, including date of VZV vaccination, is required.
- Must not be on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies
    - Intermittent corticosteroids are allowed, defined as up to 1000mg of methylprednisolone (or equivalent) daily x 3-5 days
- Must have baseline ophthalmologic evaluation of the macula. Additional caution should be taken with patients with a history of diabetes mellitus or uveitis, as they are at increased risk for macular edema.

- Members with pre-existing lung disease, such as asthma or chronic obstructive pulmonary disease, must have baseline spirometric evaluation of respiratory function and evaluation of diffusion lung capacity for carbon monoxide (DLCO)
- Must not have experienced any of the following in the past 6 months: myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Must not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless a patient has a functioning pacemaker
- Must not be treated currently with Class Ia or Class III anti-arrhythmic medication
- Must not have or have a history of progressive multifocal leukoencephalopathy (PML) or posterior reversible encephalopathy syndrome (PRES)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Documentation from the provider that the member's disease course has stabilized or improved based upon the prescriber's assessment while on therapy
- Documentation that there is no evidence of active infection
- Documentation that there is no evidence of progressive multifocal leukoencephalopathy (PML) or posterior reversible encephalopathy syndrome (PRES)
- Documentation that the member has had a follow-up ophthalmologic evaluation of the macula within 3-4 months of starting therapy (only required for first reauthorization)
- Documentation that the member is not on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies
    - Intermittent corticosteroids are allowed, defined as up to 1000mg of methylprednisolone (or equivalent) daily x 3-5 days
- Documentation that the member's CBC and transaminase/bilirubin levels are being monitored consistently

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 4 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Capsule	30 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation: May 2018.
2. Kappos L, Radue E, O'Connor P, et al. A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis. N Engl J Med 2010;362:387-401.
3. Cohen J, Barkhof F, Comi G, et al. Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis. N Engl J Med 2010;362:402-415.
4. Boulton C, Olivier JD, Meiser K, et al. Tolerability and pulmonary pharmacodynamics effects during treatment initiation of once-daily oral fingolimod in subjections with moderate asthma. Clin Pharm Drug Devel 2013;2(1):2-10.
5. Comi C, O'Connor P, Montalban X, et al. Phase II study of oral fingolimod (FTY720) in multiple sclerosis: 3-year results. Multiple Sclerosis 2010;16(2):197-207.

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 12/17, 05/18, 9/18 (effective 1/1/19)*