COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 3/13/2023 Notification Posted: 1/27/2023

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Revisions are effective the first of the month following a 45-day notification and comment period.

UM PROGRAM CRITERIA REVISED			
Gilenya (fingolimod)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Gilenya	- Updated medication cost based on AWP for 2023 - Updated generic vs brand criteria to align with other specialty MS medications on formulary - Updated continuation criteria to include MRI results every 24 months		

Prior Authorization Approval Criteria

Gilenya (fingolimod)

Generic name: Fingolimod
Brand name: Gilenya
Medispan GPI: 6240702510**** MONY
Medication class: Sphingosine 1-Phosphate (S1P) Receptor Modulator
FDA-approved uses: **Multiple sclerosis; relapsing**

Usual dose range:
Adults 0.5mg daily
Pediatric (Children ≥10 years and Adolescents) ≤40 kg: Capsule, orally disintegrating tablet: Oral: 0.25mg once daily

>40 kg: Capsule: Oral: 0.5mg once daily

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost (AWP): Brand- $152,175 per year
Generic- $9,490 per year

Criteria for Multiple Sclerosis (MS), relapsing

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed, change from brand to generic formulations may be required
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Must be 10 years of age or older.
- Must be prescribed after a consultation with a neurologist or a MS specialist.
- Documentation confirming that the patient has experienced a clinical episode and has MRI features consistent with relapsing forms of MS required for review.
    - McDonald diagnostic criteria preferred, but not required
- For brand Gilenya (new starts), patient must try/fail generic Gilenya – AND – one other preferred generic MS medication (dimethyl fumarate or glatiramer)
- For brand Gilenya (currently stable), prescriber must submit clinical documentation confirming intolerance to the generic formulation.
    - Intolerance defined as hypersensitivity

Criteria continuation of therapy

- Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.
- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes from an encounter within the last 12 months required for all annual reviews.
- Patient must be evaluated by neurology or a MS disease state specialist at least annually.
- Patient must have an updated MRI at least every 24 months.

Contraindications:

- Hypersensitivity to fingolimod (including rash, urticaria, and angioedema) or any component of the formulation; myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or New York Heart Association class III/IV heart failure in the past 6 months; Mobitz Type II second- or third-degree atrioventricular block or sick sinus syndrome (unless patient has a functioning pacemaker); baseline QTc interval ≥500 msec; concurrent use of a class Ia or III antiarrhythmic.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.

Special Considerations:

- DAW-1 (prescriber requests brand): see above information in first section
- Additional warnings for: bradyarrhythmia and atrioventricular blocks, infections, Progressive Multifocal Leukoencephalopathy, macular edema, liver injury, posterior reversible encephalopathy syndrome, respiratory effects, fetal risk, Tumefactive Multiple Sclerosis, increased blood pressure, and malignancies
- Pregnancy: Gilenya may cause fetal harm when administered to a pregnant woman. In females planning to become pregnant, Gilenya should be stopped 2 months before planned conception
- Lactation: There are no data on the presence of fingolimod in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Fingolimod is excreted in the milk of treated rats
- Drug Interactions:
    - QT prolonging drugs: The initiation of Gilenya treatment results in decreased heart rate and may prolong the QT interval, patients on QT prolonging drugs with a known risk of torsades de pointes

(e.g., citalopram, chlorpromazine, haloperidol, methadone, erythromycin) should be monitored overnight with continuous ECG in a medical facility
- Ketoconazole: The blood levels of fingolimod and fingolimod-phosphate are increased by 1.7-fold when used concomitantly with ketoconazole. Monitor closely if Gilenya and systemic ketoconazole are used concomitantly
- Vaccines: Gilenya reduces the immune response to vaccination. Vaccination may be less effective during and for up to 2 months after discontinuation of treatment with Gilenya
- Antineoplastic, Immunosuppressive, or Immune-Modulating Therapies: Antineoplastic, immune-modulating, or immunosuppressive therapies, (including corticosteroids) are expected to increase the risk of immunosuppression, and the risk of additive immune system effects must be considered if these therapies are coadministered with Gilenya. When switching from drugs with prolonged immune effects, such as natalizumab, teriflunomide or mitoxantrone, the duration and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects when initiating Gilenya
- Drugs That Slow Heart Rate or Atrioventricular Conduction (e.g., beta blockers or diltiazem): initiation of Gilenya treatment may result in an additional decrease in heart rate, concomitant use of these drugs during Gilenya initiation may be associated with severe bradycardia or heart block

References:

1. Gilenya [package insert]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2019.

MedOne Clinical Review Subcommittee approval: Date: 1-1-17

Initial adoption:	1-1-17
Revised:	1-18-23
1-18-23	- Updated medication cost based on AWP for 2023 - Updated generic vs brand criteria to align with other specialty MS medications on formulary - Updated continuation criteria to include MRI results every 24 months
Effective Date (most recent revisions):	3-13-23

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