MEDICATION POLICY

Generic Name: Fingolimod

Therapeutic Class or Brand Name: Gilenya®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 5/09/2018

GPI Code: 6240702510

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

I. Documented diagnosis of a relapsing form of multiple sclerosis.

II. Minimum age requirement: 10 years old.

III. Prescribing physician must be a neurologist or a multiple sclerosis physician specialist.

IV. Documented trial and failure of, intolerance to, or contraindication to two preferred products (refer to plan document for the list of preferred products).

Exclusion Criteria:

- Coadministration of Gilenya® with another disease-modifying multiple sclerosis therapy such as Aubagio® (teriflunomide), Avonex® (interferon beta-1a), Betaseron® (interferon beta-1b), Copaxone® (glatiramer), Extavia® (interferon beta-1b), Glatopa™ (glatiramer), Lemtrada® (alemtuzumab), Novantrone® (mitoxantrone), Ocrevus™ (ocrelizumab), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tecfidera® (dimethyl fumarate), or Tysabri® (natalizumab)
- Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
- History or presence of Mobitz Type II 2nd degree or 3rd degree AV block, or sick sinus syndrome, unless patient has a pacemaker.
- Baseline QTc interval ≥ 500 ms.
- Treatment with Class Ia or Class III anti-arrhythmic drugs.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Quantities of up to 30 capsules per 30 days.

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/thpp-gilenya-fingolimod.
2. NPS.
3. http://www.pharma.us.novartis.com/product/pi/pdf/gilenya.pdf.

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Historical Tracking Of Changes Made To Policy	
5/09/2018	1. **Changed** minimum age requirement to 10 years old **under Prior Authorization Criteria** 2. **Deleted** "or Zinbryta™ (daclizumab)" **from Exclusion Criteria** 3. **Deleted** "blue.regence.com/trgmedpol/drugs/dru229.pdf" **and added "**https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/thpp-gilenya-fingolimod." **Under References**
11/16/2017	1. **Added** "Ocrevus™ (ocrelizumab)" **to list of drugs following the statement** "Coadministration of Gilenya® with another disease-modifying multiple sclerosis therapy such as…" **under Exclusion Criteria**.
5/28/2016	1. **Changed** "I. Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting or secondary progressive multiple sclerosis)" **to** "I. Documented diagnosis of a relapsing form of multiple sclerosis" **under Prior Authorization Criteria**. 2. **Changed** "IV. Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (refer to plan document for the list of preferred products)" **to** "IV. Documented trial and failure of, intolerance to, or contraindication to two preferred products (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 3. **Changed** "Gilenya® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies [i.e. Alemtuzumab (Lemtrada™), Dimethyl fumarate (Tecfidera®), Glatiramer acetate (Copaxone®), Interferon beta-1a (Avonex®, Rebif®), Interferon beta-1b (Betaseron®, Extavia®), Mitoxantrone (Novantrone®), Natalizumab (Tysabri®), Peginterferon beta-1a (Plegridy™), Teriflunomide (Aubagio®)]" **to** "Coadministration of Gilenya® with another disease-modifying multiple sclerosis therapy such as Aubagio® (teriflunomide), Avonex® (interferon beta-1a), Betaseron® (interferon beta-1b), Copaxone® (glatiramer), Extavia® (interferon beta-1b), Glatopa™ (glatiramer), Lemtrada® (alemtuzumab), Novantrone® (mitoxantrone), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tecfidera® (dimethyl fumarate), Tysabri® (natalizumab), or Zinbryta™ (daclizumab)" **under Exclusion Criteria**. 4. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MS%20Oral%20Drugs%20DRAFT%20201 5-02-12.pdf" **from under References** (link no longer valid).
3/30/2015	1. **Changed** "Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (Avonex® and Copaxone®)" **to** "Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 2. **Added** "Alemtuzumab (Lemtrada™)" **and "**Peginterferon beta-1a (Plegridy™)" **to list of examples following** "Gilenya® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies" **under Exclusion Criteria**. 3. **Changed** "Quantities of up to 28 capsules per 28 days" **to** "Quantities of up to 30 capsules per 30 days" **under Quantity/Days Supply Restrictions**. 4. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Gilenya.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MS%20Oral%20Drugs%20DRAFT%20201 5-02-12.pdf" **under References**.
1/14/2014	1. **Adapted policy to new format.** 2. **Changed Prior Authorization Criteria from:** "Documented diagnosis of relapsing-remitting multiple sclerosis; Dose limited to less than or equal to 0.5mg once daily; A written plan to monitor for bradyarrythmia in-office or clinic for six hours following the first dose; The following baseline test values need to be within normal limits within the preceding six months: Complete Blood Count (CBC): WBC between 3,200 and 9,800 cells/mm3, Hgb between 12 and 18 g/dL, Hct between 33 and 49%, Platelets between 140,000 and 440,000 cells/microL, Liver Function Tests (LFT): AST and/or ALT between 0 and 35 IU/L, Electrocardiogram (ECG) within

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Historical Tracking Of Changes Made To Policy	
	normal limits, Ophthalmic exam within normal limits; Minimum age requirement: 18 years old" **to:** . "Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting or secondary progressive multiple sclerosis); Minimum age requirement: 18 years old; Prescribing physician must be a neurologist or a multiple sclerosis physician specialist; Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (Avonex® and Copaxone®)". 3. **Changed Exclusion Criteria from** "N/A" **to** "Gilenya® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies [i.e. Dimethyl fumarate (Tecfidera®), Glatiramer acetate (Copaxone®), Interferon beta-1a (Avonex®, Rebif®), Interferon beta-1b (Betaseron®, Extavia®), Mitoxantrone (Novantrone®), Natalizumab (Tysabri®), Teriflunomide (Aubagio®)]; Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; History or presence of Mobitz Type II 2nd degree or 3rd degree AV block, or sick sinus syndrome, unless patient has a pacemaker; Baseline QTc interval ≥500 ms; Treatment with Class Ia or Class III anti-arrhythmic drugs". 4. **Changed Quantity/Days Supply Restrictions from** "30 capsules per 30 days" **to** "Quantities of up to 28 capsules per 28 days". 5. **Changed Authorization under Approval Length from:** "Initial authorization will be granted for three months. If baseline CBC, LFT, ECG, and/or ophthalmic exam results are not within normal limits, compelling rationale for initiation of therapy must be provided in a detailed letter of medical necessity" **to:** "1 year". 6. **Changed Re-Authorization under Approval Length from:** "Re-authorization will be granted in one-year increments. Re-authorization requires updated CBC, LFT, ECG, and ophthalmic exam. Re-authorization will be granted if values for CBC, LFT, ECG, and ophthalmic exam remain within normal limits. If updated CBC, LFT, ECG, and/or ophthalmic exam results are not within normal limits, compelling rationale for continuation of therapy must be provided in a detailed letter of medical necessity" **to:** "An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective". 7. **Updated references** to include package insert.