



## 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:** 5/28/16

**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: 18 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), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tecfidera® (dimethyl fumarate), Tysabri® (natalizumab), or Zinbryta™ (daclizumab).
- 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  $\geq$  500 ms.
- Treatment with Class Ia or Class III anti-arrhythmic drugs.

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

---

*Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.*



## MEDICATION POLICY

- 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. [blue.regence.com/trgmedpol/drugs/dru229.pdf](http://blue.regence.com/trgmedpol/drugs/dru229.pdf).
2. NPS.
3. <http://www.pharma.us.novartis.com/product/pi/pdf/gilenya.pdf>.

---

*Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.*



## MEDICATION POLICY

<b>Historical Tracking Of Changes Made To Policy</b>	
5/28/2016	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “I. Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting or secondary progressive multiple sclerosis)” <b>to</b> “I. Documented diagnosis of a relapsing form of multiple sclerosis” <b>under Prior Authorization Criteria.</b></li> <li>2. <b>Changed</b> “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)” <b>to</b> “IV. Documented trial and failure of, intolerance to, or contraindication to two preferred products (refer to plan document for the list of preferred products)” <b>under Prior Authorization Criteria.</b></li> <li>3. <b>Changed</b> “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®)]” <b>to</b> “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)” <b>under Exclusion Criteria.</b></li> <li>4. <b>Removed</b>  <a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MS%20Oral%20Drugs%20DRAFT%202015-02-12.pdf">“https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MS%20Oral%20Drugs%20DRAFT%202015-02-12.pdf”</a> <b>from under References</b> (link no longer valid).</li> </ol>
3/30/2015	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (Avonex® and Copaxone®)” <b>to</b> “Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (refer to plan document for the list of preferred products)” <b>under Prior Authorization Criteria.</b></li> <li>2. <b>Added</b> “Alemtuzumab (Lemtrada™)” <b>and</b> “Peginterferon beta-1a (Plegridy™)” <b>to list of examples following</b> “Gilenya® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies” <b>under Exclusion Criteria.</b></li> <li>3. <b>Changed</b> “Quantities of up to 28 capsules per 28 days” <b>to</b> “Quantities of up to 30 capsules per 30 days” <b>under Quantity/Days Supply Restrictions.</b></li> <li>4. <b>Updated</b> “<a href="http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Gilenya.pdf">http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Gilenya.pdf</a>” <b>to</b> “<a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MS%20Oral%20Drugs%20DRAFT%202015-02-12.pdf">https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MS%20Oral%20Drugs%20DRAFT%202015-02-12.pdf</a>” <b>under References.</b></li> </ol>
1/14/2014	<ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Changed Prior Authorization Criteria from:</b>            “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 bradyarrhythmia 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/mm<sup>3</sup>, 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 normal limits, Ophthalmic exam within normal limits; Minimum age requirement: 18 years old”  <b>to:</b>            “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®)”.</li> <li>3. <b>Changed Exclusion Criteria from</b> “N/A” <b>to</b> “Gilenya® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies [i.e. Dimethyl fumarate</li> </ol>

*Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.*



## MEDICATION POLICY

### *Historical Tracking Of Changes Made To Policy*

	<p>(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 <math>\geq 500</math> ms; Treatment with Class Ia or Class III anti-arrhythmic drugs”.</p> <p>4. <b>Changed Quantity/Days Supply Restrictions</b> from “30 capsules per 30 days” to “Quantities of up to 28 capsules per 28 days”.</p> <p>5. <b>Changed Authorization under Approval Length from:</b> “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” <b>to:</b> “1 year”.</p> <p>6. <b>Changed Re-Authorization under Approval Length from:</b> “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” <b>to:</b> “An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective”.</p> <p>7. <b>Updated references</b> to include package insert.</p>
--	--

---

*Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.*