**PHARMACY POLICY STATEMENT**

**Ohio Medicaid**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Gilenya (fingolimod)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Must use valid NDC code</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Preferred Product)</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>30 caps per 30 days</td>
</tr>
</tbody>
</table>

**LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY**

- Click Here

Gilenya (fingolimod) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**RELAPSING-REMITTING MULTIPLE SCLEROSIS, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS**

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
4. Member must **not** have experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure within the last 6 months; AND
5. Member must **not** have history or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker; AND
6. Member must have documentation in chart notes that baseline QTc interval is not greater than 500 msec; AND
7. Member must **not** currently be receiving treatment with Class Ia or Class III anti-arrhythmic drugs.
8. **Dosage allowed:** 0.5 mg orally once daily.

*If member meets all the requirements listed above, the medication will be approved for 12 months.*

For **reauthorization**:
1. Member must be in compliance with all other initial criteria.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

CareSource considers Gilenya (fingolimod) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/12/2017</td>
<td>New policy for Gilenya created. Not covered diagnosis added. Contraindications added in criteria. Baseline QTc interval required.</td>
</tr>
<tr>
<td>12/06/2017</td>
<td>Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer required.</td>
</tr>
</tbody>
</table>

References:

Effective date: 12/20/2017
Revised date: 12/06/2017