Overview
Gilenya is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with Gilenya, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs OR Approval may be granted when the following criteria are met:
- The member has a diagnosis of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
- The prescribing physician is a neurologist or MS specialist

Continuation of Therapy
Reauthorization requires physician documentation of improvement of overall disease activity, including a reduction in clinical exacerbations and/or prevention of worsening of physical disability.

Limitations
1. Approvals will be granted for 12 months
2. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Gilenya 0.5mg</th>
<th>30 capsules per 30 days</th>
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<tbody>
<tr>
<td>Gilenya 0.25mg</td>
<td>30 capsules per 30 days</td>
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References


Review History

04/25/2011 – Reviewed
06/06/2011 – Effective
04/23/2012 – Reviewed
04/22/2013 – Reviewed
11/04/2013 – Updated (removed injectable requirement; 09/23/13 P&T Meeting)
04/28/2014 – Reviewed
04/27/2015 – Reviewed
04/25/2016 – Reviewed
04/24/2016 – Reviewed
04/17/2019 – Reviewed in P&T Meeting
05/20/2020 – Reviewed and Updated May P&T Mtg; references updated; removed recommended dosing and monitoring; added QL to ‘Limitations’; updated FDA approved indications to include clinically isolated syndrome and active secondary progressive disease. Effective 8/1/20.

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