Multiple Sclerosis

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Multiple Sclerosis drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The following is a listing of the individual drug therapy products and their Food and Drug Administration (FDA) approved indications.

**Aubagio®** (teriflunomide), **Copaxone®** (glatiramer acetate), **Gilenya™** (fingolimod), **Glatopa™** (glatiramer acetate, 20 mg), **Plegridy™** (peginterferon beta-1α), **Rebif®** (interferon beta-1α), **Tecfidera™** (dimethyl fumarate) and **Tysabri®** (natalizumab) are approved for the treatment of relapsing forms of MS.

**Avonex®** (interferon beta-1α), **Betaseron®** (interferon beta-1β), and **Extavia®** (interferon beta-1β) are approved for the treatment of relapsing forms of MS and the first clinical episode of MS.

**Lemtrada™** (alemtuzumab) is approved for the treatment of relapsing forms of MS in patients who have had inadequate response to two or more drugs for the treatment of MS.

POLICY

I. **Glatopa™** and **Copaxone®** (glatiramer acetate, 20 mg) may be considered medically necessary when used as monotherapy for a patient with a diagnosis of a relapsing form of multiple sclerosis (MS), OR who is experiencing a clinically isolated syndrome with magnetic resonance imaging (MRI) consistent with MS.

   Approval will be for lifetime

II. **Avonex®** (interferon beta-1α), **Betaseron®** (interferon beta-1β), **Copaxone®** (glatiramer acetate, 40 mg), **Extavia®** (interferon beta-1β), **Plegridy™** (peginterferon beta-1α), **Rebif®** (interferon beta-1α), may be considered medically necessary when used as monotherapy for a patient with a diagnosis of a relapsing form of MS, OR who is experiencing a clinically isolated syndrome with MRI results consistent with MS, when the patient has tried and failed the preferred MS therapy: glatiramer acetate 20 mg (Glatopa™ or Copaxone®), unless there is a contraindication to use.

   Approval will be for lifetime
III. **Aubagio** (teriflunomide), **Gilenya** (fingolimod) **Tecfidera** (dimethyl fumarate) may be considered *medically necessary* for use as monotherapy for the treatment of relapsing forms of MS when the *treatment naive* patient has tried and failed the preferred MS therapy: glatiramer acetate 20 mg (Glatopa™ or Copaxone®), unless there is a contraindication to use. The trial and failure of glatiramer is not required for patients who are not treatment naive.

IV. **Lemtrada** (alemtuzumab) and **Tysabri** (natalizumab)* may be considered *medically necessary* as monotherapy for the treatment of MS when the patient has tried and failed two MS therapies, or when the patient has evidence of highly active disease despite glatiramer or interferon-β as demonstrated by 1 relapse in the previous year and either a) ≥1 gadolinium-enhancing MRI lesion or (b) at least 9 T2-hyperintensive lesions on cranial MRI.

**Approval** will be for lifetime

*Tysabri is also considered medically necessary for the treatment of Crohn’s Disease (CD) refractory to other agents

The aforementioned drugs are considered not *medically necessary* for patients who do not meet the criteria set forth above.

**Prior approval is required.** Submit a prior approval/treatment request now.

**Quantity limits apply:**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aubagio</strong></td>
<td>teriflunomide</td>
<td>30 tablets per 30 days</td>
</tr>
<tr>
<td><strong>Avonex</strong></td>
<td>interferon beta-1α</td>
<td>4 vials per 28 days</td>
</tr>
<tr>
<td><strong>Betaseron</strong></td>
<td>interferon beta-1β</td>
<td>15 vials per 30 days</td>
</tr>
<tr>
<td><strong>Copaxone® 20 mg/Glatopa™ 20mg</strong></td>
<td>glatiramer acetate</td>
<td>30 syringes (1 kit) per 30 days</td>
</tr>
<tr>
<td><strong>Copaxone® 40 mg</strong></td>
<td>glatiramer acetate</td>
<td>12 syringes per 28 days</td>
</tr>
<tr>
<td><strong>Extavia®</strong></td>
<td>interferon beta-1β</td>
<td>15 vials per 30 days</td>
</tr>
<tr>
<td><strong>Gilenya™</strong></td>
<td>fingolimod</td>
<td>30 capsules per 30 days</td>
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</table>
| **Plegridy™** | peginterferon beta-1α | Initiation of therapy: 1 starter pack per first 28 days  
Maintenance: 2 pens per 28 days |
| **Rebif®** | interferon beta-1α | 12 vials per 28 days              |
| **Tecfidera™** | dimethyl fumarate | Initiation of therapy: 1 starter pack per first 28 days  
Maintenance: 60 capsules per 30 days |
| **Tysabri®** | natalizumab | 1 vial per 28 days                 |
To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.

- Q9979 - Injection, alemtuzumab, 1 mg
- J2323, natalizumab, 1 mg

REFERENCES

- Gilenya [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2012.
