I. Length of Authorization

Coverage will be approved for 8 doses only; to be administered within a 2 year period and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- First Course*
  - Lemtrada 12 mg/1.2 ml: 5 vials per 365 days (1 vial daily x 5 days per year)
- Second Course*
  - Lemtrada 12 mg/1.2 ml: 3 vials per 365 days (1 vial daily x 3 days per year)
  
  *8 doses only within a 2 year period

B. Max Units (per dose and over time) [Medical Benefit]:

- 96 billable units total (12 billable units per dose)
  - To be administered within a 2 year period (1 dose daily x 5 days followed by 1 dose daily x 3 days, one year later)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older: AND
- Patient has received a baseline skin exam for melanoma: AND
- Patient must not have human immunodeficiency virus infection: AND
- Patient should be screened for the presence of tuberculosis according to local guidelines: AND
- Patient will not receive live vaccines following a course of Lemtrada: AND
- Patient has been diagnosed* with a relapsing form of multiple sclerosis [i.e. relapsing-remitting disease (RRMS) or secondary progressive MS (SPMS) with relapses]: AND
- Confirmed diagnosis* of MS as documented by laboratory report (i.e., MRI): AND
- Prescriber and patient must be enrolled in and meet the conditions of the LEMTRADA REMS program: AND
- Must be used as single agent therapy: AND
- Patient should have had an inadequate response to an adequate trial of two or more drugs indicated for the treatment of MS: AND

One of which must be natalizumab (Tysabri) unless contraindicated or not tolerated
† FDA Approved Indication(s)

*Definitive diagnosis of MS with a relapsing-remitting course is based upon BOTH dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).

<table>
<thead>
<tr>
<th>Dissemination in time</th>
<th>Dissemination in space</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Development/appearance of new CNS lesions over time)</td>
<td>(Development of lesions in distinct anatomical locations within the CNS: multifocal)</td>
</tr>
</tbody>
</table>
| • ≥ 2 clinical attacks: **OR**  
  • 1 clinical attack **AND** one of the following:  
    ○ MRI indicating simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up MRI compared to baseline scan  
    ○ CSP-specific oligoclonal bands | • ≥ 2 lesions: **OR**  
  • 1 lesion **AND** one of the following:  
    ○ Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location  
    ○ MRI indicating ≥ 1 T2-hyperintense lesions characteristic of MS in ≥ 2 of 4 areas of the CNS (periventricular, cortical or juxtacortical, infratentorial, or spinal cord) |

IV. **Renewal Criteria**

Coverage cannot be renewed

V. **Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
</table>
| All Indications | Administered by intravenous infusion over 4 hours for 2 treatment courses:  
  • First course: 12 mg/day on 5 consecutive days (60 mg total dose)  
  • Second course: 12 mg/day on 3 consecutive days (36 mg total dose), 12 months after first treatment course. |

VI. **Billing Code/Availability Information**

**Jcode:**  
• J0202 - Injection, alemtuzumab, 1 mg; 1mg = 1 billable unit  

**NDC:**  
• Lemtrada 12 mg/1.2 mL single-use vial: 58468-0200-xx

VII. **References**


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G35</td>
<td>Multiple Sclerosis</td>
</tr>
</tbody>
</table>
Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

<table>
<thead>
<tr>
<th>Jurisdiction(s):</th>
<th>NCD/LCD Document(s):</th>
<th>A55310</th>
</tr>
</thead>
</table>

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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</tbody>
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