Lemtrada® (alemtuzumab)

(Intravenous)

Last Review Date: January 1, 2020

Number: MG.MM.PH.90

Medical Guideline Disclaimer

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Definition

Lemtrada® is a recombinant monoclonal antibody that binds to CD52 and causes antibody-dependent cellular cytolysis, complement-mediated lysis, and depletes circulating T and B lymphocytes.

Length of Authorization

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

Dosing Limits

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)

Guideline

I. 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**

**Multiple Sclerosis †**

- 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

* 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>
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<tr>
<td>≥ 2 clinical attacks; <strong>OR</strong></td>
<td>≥ 2 lesions; <strong>OR</strong></td>
</tr>
<tr>
<td>1 clinical attack <strong>AND</strong> one of the following:</td>
<td>1 lesion <strong>AND</strong> one of the following:</td>
</tr>
<tr>
<td>o 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</td>
<td>o Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location</td>
</tr>
<tr>
<td>o CSF-specific oligoclonal bands</td>
<td>o 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)</td>
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</tbody>
</table>

II. **RENEWAL CRITERIA**

Coverage cannot be renewed

**Dosing/Administration**

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

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0202</td>
<td>Injection, alemtuzumab, 1 mg; 1mg = 1 billable unit</td>
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</tbody>
</table>

Applicable NDC’s

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>58468-0200-xx</td>
<td>Lemtrada 12 mg/1.2 mL single-use vial</td>
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</table>

ICD-10

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G35</td>
<td>Multiple Sclerosis</td>
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</tbody>
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Revision History

N/A

References


