Medical Policy:

Lemtrada® (alemtuzumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.90	March 21, 2025	

Definitions

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 [Medical Benefit]

Max Units (per dose and over time):

- 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:

1. Patient is 18 years or older; **AND**
2. Patient has received a baseline skin exam for melanoma; and will receive yearly skin exams while on therapy; **AND**
3. Patient must not have human immunodeficiency virus infection; **AND**
4. Patient should be screened for the presence of tuberculosis according to local guidelines and will receive ongoing monitoring for the presence of TB during treatment; **AND**
5. Patient will not receive live vaccines while on therapy or within 6 weeks prior to initiation of treatment**; AND**
6. Patient has been evaluated and screened for the presence of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment; **AND**
7. Patient has a baseline electrocardiogram (ECG); **AND**
8. Patient has a baseline urine protein to creatinine ratio AND thyroid-stimulating hormone (TSH) level prior to initiation of treatment and will receive ongoing laboratory monitoring during treatment; **AND**
9. Patient will receive anti-viral prophylaxis for herpetic viral infections initiated on the first day of treatment and continued for two months following treatment (or until the CD4+ lymphocyte count is ≥ 200 cells/mcL; **AND**

Multiple Sclerosis †

1. 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**
2. Confirmed diagnosis***** of MS as documented by laboratory report (i.e., MRI); **AND**
3. Prescriber and patient must be enrolled in and meet the conditions of the LEMTRADA REMS program; **AND**
4. Must be used as single agent therapy; **AND**
5. Patient should have had an inadequate response to an adequate trial of **TWO** or more drugs indicated for the treatment of MS ; **AND**
6. Will not be used for the treatment of clinically isolated syndrome (CIS)

† 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).**	
Dissemination in time (*Development/appearance of new CNS lesions over time*)	**Dissemination in space** (*Development of lesions in distinct anatomical locations within the CNS; multifocal*)

• ≥ 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
  ○ CSF-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)

**Active secondary progressive MS (SPMS) is defined as the following:
• Expanded Disability Status Scale (EDSS) score ≥ 3.0; AND • Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤5.5 or increase by 0.5 in patients with EDSS ≥6); AND o ≥ 1 relapse within the previous 2 years; OR o Patient has gadolinium-enhancing activity OR new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

II. RENEWAL CRITERIA

Coverage cannot be renewed

Dosing/Administration

Indication	Dose
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.

Applicable Procedure Codes

Code	Description
J0202	Injection, alemtuzumab, 1 mg; 1mg = 1 billable unit

Applicable NDCs

Code	Description
58468-0200-01	Lemtrada 12 mg/1.2 mL single-use vial

ICD-10 Diagnoses

Code	Description
G35	Multiple Sclerosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/21/2025	Annual Review: Added SPMS chart. Updated the following statement for clarification: “Patient will not receive live vaccines following a course of Lemtrada; AND” updated to: “ Patient will not receive live vaccines while on therapy or within 6 weeks prior to initiation of treatment; AND”
EmblemHealth & ConnectiCare	2/5/2024	Annual Review: Initial Criteria: Added: “ and will receive yearly exams” to the statement: “Patient has received a baseline skin exam for melanoma; and will receive yearly skin exams while on therapy;” Added” and will receive ongoing monitoring for the presence of TB during treatment;” Added: “Patient has been evaluated and screened for the presence

		of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment; AND Patient has a baseline electrocardiogram (ECG); AND Patient has a baseline urine protein to creatinine ratio AND thyroid-stimulating hormone (TSH) level prior to initiation of treatment and will receive ongoing laboratory monitoring during treatment; AND Patient will receive anti-viral prophylaxis for herpetic viral infections initiated on the first day of treatment and continued for two months following treatment (or until the CD4+ lymphocyte count is > 200 cells/mcL; AND Will not be used for the treatment of clinically isolated syndrome (CIS) "
EmblemHealth & ConnectiCare	6/12/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	09/06/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	01/01/2020	Annual review

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