

## Medical Policy:

### Lemtrada® (alemtuzumab) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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## Definitions

Lemtrada® is a recombinant monoclonal antibody that binds to CD52 and causes antibody-dependent cellular cytotoxicity, 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  $\geq 200$  cells/mL; **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).**

<b><u>Dissemination in time</u></b> (Development/appearance of new CNS lesions over time)	<b><u>Dissemination in space</u></b> (Development of lesions in distinct anatomical locations within the CNS; multifocal)
<ul style="list-style-type: none"><li>• <math>\geq 2</math> clinical attacks; <b>OR</b></li><li>• 1 clinical attack <b>AND</b> one of the following:<ul style="list-style-type: none"><li>○ 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</li><li>○ CSF-specific oligoclonal bands</li></ul></li></ul>	<ul style="list-style-type: none"><li>• <math>\geq 2</math> lesions; <b>OR</b></li><li>• 1 lesion <b>AND</b> one of the following:<ul style="list-style-type: none"><li>○ Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location</li><li>○ MRI indicating <math>\geq 1</math> T2-hyperintense lesions characteristic of MS in <math>\geq 2</math> of 4 areas of the CNS (periventricular, cortical or juxtacortical, infratentorial, or spinal cord)</li></ul></li></ul>

**\*\*Active secondary progressive MS (SPMS) is defined as the following:**

- Expanded Disability Status Scale (EDSS) score  $\geq 3.0$ ; AND
- Disease is progressive  $\geq 3$  months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS  $\leq 5.5$  or increase by 0.5 in patients with EDSS  $\geq 6$ ); AND
  - o  $\geq 1$  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: <ul style="list-style-type: none"><li>▪ First course: 12 mg/day on 5 consecutive days (60 mg total dose)</li><li>▪ Second course: 12 mg/day on 3 consecutive days (36 mg total dose), 12 months after first treatment course.</li></ul>

### 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

## References

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