

Medical Policy:

Lemtrada® (alemtuzumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.90	February 5, 2024	

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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.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 following a course of Lemtrada; **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).**

<u>Dissemination in time</u> <i>(Development/appearance of new CNS lesions over time)</i>	<u>Dissemination in space</u> <i>(Development of lesions in distinct anatomical locations within the CNS; multifocal)</i>
<ul style="list-style-type: none"> • ≥ 2 clinical attacks; OR • 1 clinical attack AND one of the following: <ul style="list-style-type: none"> ○ 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 	<ul style="list-style-type: none"> • ≥ 2 lesions; OR • 1 lesion AND one of the following: <ul style="list-style-type: none"> ○ 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

○ CSF-specific oligoclonal bands	(periventricular, cortical or juxtacortical, infratentorial, or spinal cord)
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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"> ▪ 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	2/5/2024	Annual Review:Initial Criteria: Added: " and will received 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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