Lemtrada® (alemtuzumab)
(Intravenous)

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I. Length of Authorization

Coverage will be approved initially for 5 doses and may be renewed for 3 doses annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

First Course
- Lemtrada 12 mg/1.2 mL: 5 vials per 365 days (1 vial daily x 5 days per year)

Second/Subsequent Courses
- Lemtrada 12 mg/1.2 mL: 3 vials per 365 days (1 vial daily x 3 days per year)

B. Max Units (per dose and over time) [HCPCS Unit]:

- First Course
  - 60 billable units (*1 dose daily x 5 days*) during the first 12 months
- Second/Subsequent Courses
  - 36 billable units (*1 dose daily x 3 days*) every 12 months thereafter

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- 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**

Universal Criteria [1]

- Patient does not have human immunodeficiency virus infection; **AND**
- Patient has been evaluated and screened for the presence of tuberculosis (TB) prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection; **AND**

- Must not be administered concurrently, or within 6 weeks prior to treatment, with live vaccines; **AND**
- Patient has received a baseline skin exam for melanoma and will receive yearly skin exams; **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**
- Prescriber and patient must be enrolled in and meet the conditions of the LEMTRADA REMS program; **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**
- Confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); **AND**
- Must be used as single agent therapy; **AND**
- Patient must 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). [14]**

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: [11,14-16]**

- 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**

- ≥ 1 relapse within the previous 2 years; **OR**
- Patient has gadolinium-enhancing activity or new and unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

IV. Renewal Criteria [1,13]

Authorizations can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Patient has not received a dose of alemtuzumab within the past 12 months; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: immune thrombocytopenia, glomerular nephropathies, thyroid disorders, autoimmune conditions, severe infusion reactions including anaphylaxis, ischemic or hemorrhagic strokes, malignancies (e.g., thyroid cancer, melanoma, lymphoproliferative disorders/lymphoma, etc.), progressive multifocal encephalopathy, thrombotic thrombocytopenic purpura, hemophagocytic lymphohistiocytosis, acquired hemophilia A, etc.; **AND**
- Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by EDSS, timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)].
    - Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period

V. Dosage/Administration [1]

Indication	Dose
All Indications	Administer by intravenous infusion over 4 hours: ▪ 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), administered 12 months after the first treatment course. ▪ Subsequent courses: 12 mg/day on 3 consecutive days (36 mg total dose) administered , as needed, at least 12 months after the last dose of any prior treatment course.

VI. Billing Code/Availability Information

HCPCS Code:

- J0202 - Injection, alemtuzumab, 1 mg; 1mg = 1 billable unit

NDC:

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

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35	Multiple Sclerosis

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/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/LCA):

Jurisdiction(s): J, M	**NCD/LCD Document (s):** A55310
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a55310&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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