Lemtrada® (alemtuzumab)
(Intravenous)

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

Second Course*
- Lemtrada 12 mg/1.2 ml: 3 vials per 365 days (1 vial daily x 3 days per year)

*8 *doses only within a 2 year period*

B. 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)*

III. 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).**	
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)

IV. Renewal Criteria

Coverage cannot be renewed

V. Dosage/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.

VI. Billing Code/Availability Information

Jcode:

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

NDC:

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

VII. References

1. Lemtrada [package Insert]. Cambridge, MA; Genzyme Corporation.; December 2017. Accessed August 2018.
2. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan 22;58(2):169-78.
3. Coles AJ, Fox E, Vladic A, et al. Alemtuzumab more effective than interferon ß-1a at 5-year follow-up of CAMMS223 clinical trial. Neurology. 2012;78(14):1069–1078.
4. Coles AJ, Fox E, Vladic A, et al. Alemtuzumab versus interferon ß-1a in early relapsing-remitting multiple sclerosis: post-hoc and subset analyses of clinical efficacy outcomes. Lancet Neurol. 2011;10(4):338–348.
5. Coles AJ, Twyman CL, Arnold DL, et al; for CARE-MS II investigators. Alemtuzumab for patients with relapsing multiple sclerosis after disease-modifying therapy: a randomised controlled phase 3 trial. Lancet. 2012;380(9856):1829–1839.
6. Coles AJ, Compston DA, Selmaj KW, et al; for CAMMS223 Investigators. Alemtuzumab vs interferon beta-1a in early multiple sclerosis. N Engl J Med. 2008;359(17):1786–1801.
7. Cohen JA, Coles AJ, Arnold DL, et al; for CARE-MS I investigators. Alemtuzumab versus interferon beta 1a as first-line treatment for patients with relapsing-remitting multiple sclerosis: a randomised controlled phase 3 trial. Lancet. 2012;380(9856):1819–1828.
8. Fox EJ, Sullivan HC, Gazda SK, et al. A single-arm, open-label study of alemtuzumab in treatment-refractory patients with multiple sclerosis. Eur J Neurol. 2012;19(2):307–311.
9. Freedman MS, Selchen D, Arnold DL, et al. Treatment optimization in MS: Canadian MS Working Group updated recommendations. Can J Neurol Sci. 2013 May;40(3):307-23.
10. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Ann Neurol. 2011 Feb; 69(2): 292–302. doi: 10.1002/ana.22366.
11. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. Neurology. 2014 Jul 15;83(3):278-86. doi: 10.1212/WNL.0000000000000560.
12. Montalban X, Gold R, Thompson AJ, et al. (2018), ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. Eur J Neurol, 25 Iss 2, Jan2018: 215–237. doi:10.1111/ene.13536
13. Rae-Grant, A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology® 2018;90:777-788.
14. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol. 2018 Feb;17(2):162-173. doi: 10.1016/S1474-4422(17)30470-2.

15. Palmetto GBA. Billing and Coding Instructions for Lemtrada® (alemtuzumab) When Used in the Treatment of Relapsing Multiple Sclerosis (A55310). Centers for Medicare & Medicaid Services, Inc. Updated on 03/01/2018 with effective date 04/01/2018. Accessed August 2018.

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

Jurisdiction(s): J, M	**NCD/LCD Document (s):** A55310
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A55310&bc=gAAAAAAAAAAAAA==	

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