Lemtrada® (alemtuzumab)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 5 doses.
- Renewal: Prior authorization validity may be renewed for 3 doses every 12 months (365 days) thereafter.

II. Dosing Limits

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

- First Treatment Course
  - 12 billable units daily for 5 days during the first 12 months
- Second/Subsequent Treatment Courses
  - 12 billable units daily for 3 days every 12 months thereafter

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been evaluated and screened for the presence of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment; **AND**
- Member has a baseline electrocardiogram (ECG); **AND**

Universal Criteria [1]

- Member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- Member 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**
- Provider will confirm that member will not receive live vaccines while on therapy or within 6 weeks prior to initiation of treatment; **AND**
- Member has received a baseline skin exam for melanoma and will receive yearly skin exams while on therapy; **AND**

- Member 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**
- Member will have serum aminotransferases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]), alkaline phosphatase, and bilirubin levels measured at baseline and periodically throughout therapy; **AND**
- Member 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**
- Used as single agent therapy; **AND**

Multiple Sclerosis (MS) † [1,10,14,21]

- Member must have a confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); **AND**
- Member has been diagnosed with a relapsing form of multiple sclerosis [i.e., relapsing-remitting disease (RRMS) or active secondary progressive MS (SPMS)]; **AND**
- Member must have had an inadequate response to an adequate trial of two or more drugs indicated for the treatment of MS; **AND**
- Will not be used for the treatment of clinically isolated syndrome (CIS)

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1,13,19]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Member 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: immune thrombocytopenia, glomerular nephropathies including anti-glomerular basement membrane (anti-GBM) disease, thyroid disorders, autoimmune conditions (hepatitis, cytopenias [e.g., neutropenia, hemolytic anemia, and pancytopenia], encephalitis, etc.), severe infusion reactions including anaphylaxis, ischemic or hemorrhagic strokes, cervicocephalic (e.g., vertebral, carotid) arterial dissection, malignancies (e.g., thyroid cancer, melanoma, lymphoproliferative disorders/lymphoma, etc.), progressive multifocal leukoencephalopathy (PML), thrombotic thrombocytopenic purpura (TTP), hemophagocytic lymphohistiocytosis (HLH), Adult Onset Still's Disease (AOSD), acquired hemophilia A, infections (e.g., opportunistic, *Listeria monocytogenes,* herpes viral, and fungal infections, human papilloma

virus [HPV], hepatitis, etc.) acute acalculous cholecystitis, pneumonitis, immune-mediated colitis, 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 MRI, and progression of sustained impairment as evidenced by expanded disability scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)].

*Note:

- 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
Multiple Sclerosis	Administer by intravenous (IV) infusion over 4 hours: ▪ First treatment course: 12 mg/day on 5 consecutive days (60 mg total dose) ▪ Second treatment course: 12 mg/day on 3 consecutive days (36 mg total dose), administered 12 months after the first treatment course. ▪ Subsequent treatment 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; 1 billable unit = 1 mg

NDC:

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

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35.A	Relapsing-remitting multiple sclerosis
G35.B0	Primary progressive multiple sclerosis, unspecified
G35.B1	Active primary progressive multiple sclerosis
G35.B2	Non-active primary progressive multiple sclerosis
G35.C0	Secondary progressive multiple sclerosis, unspecified
G35.C1	Active secondary progressive multiple sclerosis
G35.C2	Non-active secondary progressive multiple sclerosis
G35.D	Multiple sclerosis, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document(s)**	**Contractor**
J, M	A55310	Palmetto GBA

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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