Alemtuzumab (Lemtrada®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration HCPCS: J0202 per 1 mg

Condition listed in policy (*see criteria for details*)

- Graft versus host disease
- Multiple sclerosis, relapsing (RMS)

AHFS therapeutic class: Immunomodulatory agent

Mechanism of action: CD52-directed cytolytic monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Lemtrada® (alemtuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Graft versus host disease

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)

Covered Doses
Up to 50 mg IV for 5 doses

Coverage Period
1 month

ICD-10:
D89.810, D89.12, D89.813, T86.09

Multiple sclerosis, relapsing (RMS)

1. Treatment of relapsing forms of multiple sclerosis, **AND**
2. Patient had an inadequate response, intolerance, or contraindication to at least two prior MS therapies, including at least one BSC-preferred agent: Extavia®, a glatiramer containing product (Glatopa, glatiramer), Gilenya®, or Tecfidera®, **AND**
3. Not used in combination with another disease-modifying therapy for multiple sclerosis (eg., Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Ocrevus, Rebif, Tecfidera, Tysabri or mitoxantrone)

Covered Doses

- First course: Up to 12 mg/day IV for five consecutive days
- Subsequent course(s): Up to 12 mg/day IV for 3 consecutive days may be administered as needed, at least 12 months after the last dose of any prior treatment course

Coverage Period

18 months [2 treatment courses administered 12 months apart]

ICD-10:

G35

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Lemtrada® (alemtuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
12mg/1.2 ml (10mg/ml) single-use vial

Campath® (alemtuzumab) Product Withdrawal

Effective September 4, 2012 Campath is no longer be available commercially, but will be provided through the manufacturer's Campath Distribution Program free of charge. Additional information can be found at: www.campath.com.

Campath (alemtuzumab) is FDA-indicated for B-Cell Chronic Lymphocytic Leukemia and is administered at a higher, more frequent dose than Lemtrada for RMS.

Lemtrada REMS program

Lemtrada is available only through a restricted program called the Lemtrada REMS Program because of the risks of autoimmunity, infusion reactions, and malignancies.
Only prescribers, patients, pharmacies and healthcare facilities certified and enrolled in the REMS program can prescribe, receive, dispense or administer Lemtrada. Healthcare facilities must have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and

cardiac and respiratory emergencies).

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Lemtrada® (alemtuzumab) [Prescribing Information]. Cambridge, MA: Genzyme Corporation, 5/2023.
- 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(17):777-788.

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee