alemtuzumab (Lemtrada)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Outpatient Facility Administration
Infusion Center Administration

Drug Details

USP Category: CENTRAL NERVOUS SYSTEM AGENTS
Mechanism of Action: CD52-directed cytolytic monoclonal antibody
HCPCS:
J0202:Injection, alemtuzumab, 1 mg
How Supplied:
12mg/1.2 ml (10mg/ml) single-use vial

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

- Graft Versus Host Disease (GVHD)
- Multiple Sclerosis, relapsing (RMS)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION
MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF LEMTRADA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (***Supporting Documentation must be submitted)***

1. **Patient is initiating therapy with the first treatment course consisting of 12 mg/day for 5 days (5 doses total).** *Additional doses beyond the first treatment course will require medical necessity for continued use in the hospital outpatient facility site of care.*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Lemtrada based on documentation submitted.**
3. **Patient continues to experience moderate to severe adverse events on Lemtrada based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**
4. **Patient is clinically unstable based on documentation submitted.**
5. **Patient is physically or cognitively unstable based on documentation submitted.**

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Graft Versus Host Disease (GVHD)

Meets medical necessity if all the following are met:

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

Covered Doses:
Up to 50 mg intravenously for 5 doses

Coverage Period:
1 month

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

Multiple Sclerosis, relapsing (RMS)

Meets medical necessity if all the following are met:

1. Treatment of relapsing forms of multiple sclerosis
2. Patient had an inadequate response, intolerance, or contraindication to at least two prior MS therapies, including at least one BSC-preferred agent: fingolimod 0.5mg, dimethyl fumarate, glatiramer, Glatopa, Avonex, Betaseron, teriflunomide, Kesimpta, Zeposia
3. Not used in combination with another disease-modifying therapy for multiple sclerosis (eg., Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, fingolimod (Gilenya, Tascenso), glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, Tysabri, Vumerity, Kesimpta, or Zeposia)

Covered Doses:

- First course: Up to 12 mg/day intravenously for five consecutive days
- Subsequent course(s): Up to 12 mg/day intravenously 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

Additional Information

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).

References

1. AHFS®. Available by subscription at http://www.lexi.com
2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Lemtrada (alemtuzumab) [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2024.
4. 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.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee