# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Alemtuzumab [Lemtrada]** | MP-RX-FP-52-23 | ☒ MMM MA ☒ MMM Multihealth |

## Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

## Service Description

This document addresses the use of Lemtrada (alemtuzumab), an infused disease modifying therapy approved by the Food and Drug Administration (FDA) for the treatment of relapsing multiple sclerosis in adults, including relapsing-remitting disease or active secondary progressive disease. Because of its safety profile, Lemtrada is not recommended to treat clinically isolated syndrome. Alemtuzumab was previously available as Campath and approved for several oncology indications. Campath is no longer commercially available but is accessible through the Campath Distribution Program to clinically appropriate individuals.

**Background Information**

Multiple sclerosis is an autoimmune inflammatory demyelinating disease of the central nervous system. Common symptoms of the disease include fatigue, numbness, coordination and balance problems, bowel and bladder dysfunction, emotional and cognitive changes, spasticity, vision problems, dizziness, sexual dysfunction and pain. Multiple sclerosis can be subdivided into four phenotypes: clinically isolated syndrome (CIS), relapsing remitting (RRMS), primary progressive (PPMS) and secondary progressive (SPMS). Relapsing multiple sclerosis (RMS) is a general term for all relapsing forms of multiple sclerosis including CIS, RRMS and active SPMS.

The treatment goal for multiple sclerosis is to prevent relapses and progressive worsening of the disease. Currently available diseasemodifying therapies (DMT) are most effective for the relapsing-remitting form of multiple sclerosis and less effective for secondary progressive decline. DMT include injectable agents, infusion therapies and oral agents.

The American Academy of Neurology (AAN) guidelines suggest starting disease-modifying therapy in individuals with relapsing forms of multiple sclerosis with recent clinical relapses or MRI activity. The guideline does not recommend one DMT over another. However, some DMTs were recommended for certain multiple sclerosis subpopulations, including a recommendation for Lemtrada for highly active disease.

The precise mechanism by which alemtuzumab (Lemtrada) exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes, and macrophages. Following cell surface binding to T and B lymphocytes, alemtuzumab results in antibody-dependent cellular cytolysis and complement-mediated lysis.

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Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Lemtrada has black box warnings for autoimmunity, infusion reactions, stroke and malignancies. Lemtrada causes serious autoimmune diseases including immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels and urinalysis with urine counts before starting treatment and then at monthly intervals until 48 months after the last dose. Lemtrada causes serious, life-threatening infusion reactions. Lemtrada must be administered in a setting equipped to manage anaphylaxis and serious infusion reactions. Individuals should be monitored for two hours after each infusion and informed infusion reactions can also occur after the monitoring period. Serious, life-threatening stroke has been reported within three days of Lemtrada administration. Educate individuals to seek immediate medical care if symptoms of stroke occur. Lemtrada may cause an increased risk of malignancies, including thyroid cancer, melanoma and lymphoproliferative disorders. Perform baseline and yearly skin exams. Because of these safety risks, Lemtrada should generally be reserved for individuals who have had an inadequate response to two or more agents indicated for the treatment of multiple sclerosis. Lemtrada is available only through restricted distribution under a Risk Evaluation Mitigation Strategy (REMS) Program.

Limitations of Use:
Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| J0202 | Injection, alemtuzumab, 1 mg [Lemtrada] |

| ICD-10 Diagnosis | Description |
|---|---|
| G35 | Multiple sclerosis |

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## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

**Alemtuzumab (Lemtrada)**

Request for Lemtrada (alemtuzumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including relapsing-remitting disease or active secondary progressive disease); **AND**
II. Individual has received prior treatment with at least two alternative drug therapies indicated for the treatment of multiple sclerosis (for example, dimethyl fumarate, interferons, glatiramer) and failed to achieve an adequate response; **AND**
III. Individual is human immunodeficiency virus (HIV) negative.

Alemtuzumab (Lemtrada) may not be approved for the following:

I. Individual is using to treat including clinically isolated syndrome; **OR**
II. Individual is using to treat primary progressive MS (PPMS); **OR**
III. Individual is using to treat non-active secondary progressive MS (SPMS); **OR**
IV. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Tecfidera, Tysabri, Vumerity and Zeposia); **OR**
V. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
VI. May not be approved when the above criteria are not met and for all other indications.

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## Limits or Restrictions

A. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

**Alemtuzumab (Lemtrada) Quantity Limit**

| Drug | Limit |
|---|---|
| Alemtuzumab (Lemtrada) | 12 mg/1.2 mL (10 mg/mL) single-use vial 3 vials per 12 months |
| **Exceptions** | |
| Initiation of Alemtuzumab (Lemtrada) therapy: May approve two additional vials (12 mg/1.2 mL) during the first treatment course in the first 12 months. | |

## Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 9, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: May 9, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 10, 2022.
5. 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. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: July 7, 2022.

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## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |

Revised: 9/27/23