Medical Drug Clinical Criteria

Subject:	Lemtrada (alemtuzumab) for the Treatment of Multiple Sclerosis		
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Overview

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. Providers seeking alemtuzumab for oncologic indications can find additional information at www.clinigengroup.com/direct/en-gb/login/ or at 877.768.4303.

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 disease-modifying 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.

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.

Clinical Criteria

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.

Lemtrada (alemtuzumab)

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.

Lemtrada (alemtuzumab) 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.

Quantity Limits

Lemtrada (alemtuzumab) Quantity Limit

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

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0202	Injection, alemtuzumab, 1 mg [Lemtrada]

ICD-10 Diagnosis

G35	Multiple sclerosis

Document History

Revised: 8/19/2022
Document History:

- 8/19/2022 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 8/20/2021 – Annual Review: Add may not approve criteria for individuals with active infection. Update drug list in exclusion for concurrent use with other disease modifying therapy. Wording and formatting changes. Coding reviewed: No changes.
- 8/21/2020 – Annual Review: Update Lemtrada criteria to align with updated labeled indication. Add may not approve criteria for CIS and non-active SPMS. Update drug list in exclusion for concurrent use with other disease modifying therapy. Administrative update to add drug specific quantity limit. Coding Reviewed: No changes.
- 08/16/2019 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes
- 08/17/2018 – Annual Review: Initial P&T review of ING-CC-0009 Lemtrada (alemtuzumab). Update criteria to align with labeled indication. Remove intolerance language from prior trial requirements to align with label.

References

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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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.