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5.60.023

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 1, 2015
Subject:	Lemtrada	**Page:**	1 of 5

Last Review Date: December 13, 2024

Lemtrada

Description

Lemtrada (alemtuzumab)

Background
Lemtrada (alemtuzumab) is multiple sclerosis (MS) disease-modifying agent. Lemtrada can potentially alter the course of disease by lessening the frequency of clinical exacerbations. Lemtrada is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Lemtrada depletes circulating T and B lymphocytes after each treatment course. Lymphocyte counts then increase over time (1).

Regulatory Status
FDA-approved indication: 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 had an inadequate response to two or more drugs indicated for the treatment of MS (1).

Limitations of Use:
Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile (1).

The Lemtrada label includes a boxed warning citing the risk of autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic

intervals for 48 months after last dose should be monitored. Lemtrada also carries a boxed warning for infusion reactions which must be administered in an appropriate setting to manage anaphylaxis or serious infusion reactions (1).

Lemtrada carries another boxed warning for an increased risk of malignancy, including thyroid cancer, melanoma, and lymphoproliferative disorders. Baseline and yearly skin exams should be done (1).

Lemtrada is contraindicated for patients with Human Immunodeficiency Virus (HIV) infection. Lemtrada can cause prolonged reductions of CD4+ lymphocyte counts which can further disease progression in patients with HIV (1).

The Lemtrada is available only through a restricted distribution program under a REMS program. The Lemtrada REMS Program, a comprehensive risk management program with frequent monitoring, is being implemented to help mitigate the serious risks associated with the medications use (1).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated (2).

Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established (1).

Related policies

Acthar Gel, Ampyra, Aubagio, Gilenya, Kesimpta, Mavenclad, Mayzent, MS Injectables, Ocrevus, Ponvory, Tecfidera, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lemtrada may be considered **medically necessary** if the conditions indicated below are met.

Lemtrada may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 17 years of age and older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including relapsing-remitting disease and active secondary progressive disease

AND ALL of the following:

1. Inadequate response to at least two drugs indicated for the treatment of MS
2. Prescriber and patient must be enrolled in Lemtrada REMS program

AND NONE of the following:

1. Clinically isolated syndrome
2. Co-infection with HIV
3. Used in combination with another MS disease modifying agent
4. Used concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 17 years of age and older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including relapsing-remitting disease and active secondary progressive disease

AND ALL of the following:

1. Prescriber and patient must be enrolled in Lemtrada REMS program

AND NONE of the following:

1. Clinically isolated syndrome
2. Co-infection with HIV

3. Used in combination with another MS disease modifying agent
4. Used concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 2 years

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Lemtrada (alemtuzumab) is indicated for the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and / or delay the accumulation of physical disability who had an inadequate response to two or more drugs indicated for the treatment of MS. Lemtrada is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of the MS injectable drugs while maintaining optimal therapeutic outcomes.

References

1. Lemtrada [package insert]. Cambridge MA: Genzyme Corp.; May 2024.
2. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. Neurological Bulletin. 2010;2(1):17-21.

Policy History

Date	Action
December 2014	Addition to PA
September 2016	Annual editorial review and reference update Policy code changed from 5.06.23 to 5.60.23
December 2016	Annual editorial review and reference update Addition of not given concurrently with live vaccines
March 2017	Annual review
June 2017	Annual review
November 2018	Annual review and reference update
March 2019	Addition of PA Renewal Requirements and changed PA duration from lifetime to 2 years
June 2019	Annual review and reference update
September 2019	Annual review
March 2020	Annual editorial review and reference update. Addition of the indications relapsing-remitting disease and active secondary progressive disease. Addition of requirement of no clinically isolated syndrome
September 2020	Annual review and reference update
December 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.60.023
June 2023	Annual review and reference update
December 2023	Annual review and reference update
June 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.