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Alemtuzumab

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Related Coverage Resources

[Medication Administration Site of Care](#)

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Overview

This policy supports medical necessity review for alemtuzumab (**Lemtrada**[®]).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Alemtuzumab (Lemtrada) is considered medically necessary when the following are met:

Multiple Sclerosis. Individual meets **ALL** of the following criteria:

- A. 17 years of age or older
- B. Documented diagnosis of **ONE** of the following:
 - a. Active Secondary Progressive Multiple Sclerosis (SPMS) (for example, SPMS with a documented relapse)
 - b. Relapsing-Remitting Multiple Sclerosis

- C. **ONE** of the following:
- i. Documentation of failure, contraindication, or intolerance to **BOTH** of the following:
 - a. dimethyl fumarate (generic for Tecfidera) [may require prior authorization] **OR** fingolimod (generic for Gilenya) [may require prior authorization]
 - b. **ONE** other disease modifying agent used for Multiple Sclerosis (see [Appendix](#) for examples)
 - ii. Previous treatment with Kesimpta (ofatumumab subcutaneous injection), Tysabri (natalizumab intravenous infusion), Tyruko (natalizumab-sztn intravenous infusion), Briumvi (ublituximab-xiij intravenous infusion), Mavenclad (cladribine tablets), or Ocrevus (ocrelizumab intravenous infusion)
 - iii. Treatment of highly-active or aggressive multiple sclerosis documented by **ONE** of the following:
 - a. Demonstration of rapidly-advancing deterioration(s) in physical functioning (for example, loss of mobility / or lower levels of ambulation, severe changes in strength or coordination)
 - b. Documentation of disabling relapse(s) with suboptimal response to systemic corticosteroids
 - c. Magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (for example, new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions)
 - d. Documentation of cognitive impairment related to multiple sclerosis (for example, deficits in short-term or long-term memory, visual spatial ability deficits)
 - iv. Currently receiving Lemtrada
- D. Medication is being prescribed by, or in consultation with, a neurologist

- Dosing.** The recommended dose of alemtuzumab (Lemtrada) is **ONE** of the following:
- A. First treatment course is 12 mg/day by intravenous infusion on 5 consecutive days (60 mg total dose)
 - B. For additional treatment courses, the dose is 12 mg/day by intravenous infusion on 3 consecutive days (36 mg total dose) administered 12 months after the last Lemtrada treatment course

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of alemtuzumab (Lemtrada) is considered medically necessary for Multiple Sclerosis when the above medical necessity criteria are met **AND** the following:

1. Documentation of beneficial response
2. At least 12 months has elapsed since the last dose of any prior Lemtrada treatment

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

- Clinically Isolated Syndrome.** Lemtrada is not recommended for use in patients with clinically isolated syndrome due to its safety profile.¹
- Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.** These agents are not indicated for use in combination (See [Appendix](#) for examples). Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy.
- Human Immunodeficiency Virus (HIV) Infection.** Use of Lemtrada is contraindicated in patients who are infected with HIV because Lemtrada causes prolonged reductions of CD4+ lymphocyte counts.¹
- Non-Relapsing Forms of Multiple Sclerosis.** The efficacy of Lemtrada has not been established in patients with multiple sclerosis with non-relapsing forms of the disease (for example, primary progressive multiple sclerosis).¹

Coding / Billing Information

Note: 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0202	Injection, alemtuzumab, 1 mg

Background

OVERVIEW

Lemtrada, a CD52-directed cytolytic monoclonal antibody, is indicated for the treatment of patients with relapsing forms of **multiple sclerosis** (MS) to include relapsing remitting disease and active secondary progressive MS in adults.¹ Lemtrada is not recommended for use in patients with clinically isolated syndrome because of its safety profile.

Due to its safety profile, use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more medications indicated for the treatment of MS.¹ Lemtrada contains the same active ingredient found in Campath® (alemtuzumab intravenous infusion). The safety and efficacy of Lemtrada have not been established in patients less than 17 years of age. Lemtrada is administered by intravenous infusion over 4 hours for two or more treatment courses: The dose for the first course is 12 mg/day on five consecutive days. The second course is 12 mg/day on three consecutive days 12 months after the first treatment course. Subsequent treatment courses of 12 mg per day on three consecutive days (36 mg total) may be given, as needed, at least 12 months after the last dose of any prior treatment course.

Disease Overview

MS is a chronic, inflammatory, demyelinating, autoimmune disease of the central nervous system that impacts almost 1,000,000 people in the US.²⁻⁴ The condition is marked by inflammation and demyelination, as well as degenerative alterations. Patients usually experience relapses and remissions in their neurological symptoms. For most patients, the onset of MS symptoms occurs when patients are 20 to 40 years of age; however, children can get MS and new onset disease can occur in older adults. The MS disease course is heterogeneous but has some patterns. Approximately 85% to 90% of patients have a relapsing pattern at onset. However, this transitions over time in patients who are untreated to a worsening with very few or no relapses or magnetic resonance imaging (MRI) activity (secondary progressive MS). Around 10% to 15% of patients have a steady progression of symptoms over time (primary progressive MS), marked by some clinical manifestations or by MRI activity. Primary progressive MS is generally diagnosed in patients on the upper level of the typical age range

(e.g., almost 40 years of age) and the distribution is equivalent among the two genders. Advances in the understanding of the MS disease process, as well as in MRI technology, spurred updated disease course descriptions in 2013,⁵ as well as in 2017.⁶ The revised disease courses are clinically isolated syndrome, relapsing remitting MS, primary progressive MS, and secondary progressive MS.²⁻⁶ Clinically isolated syndrome is now more recognized among the course descriptions of MS. It is the first clinical presentation of MS that displays characteristics of inflammatory demyelination that may possibly be MS but has yet to fulfill diagnostic criteria. It is notable that the other MS designations can be further characterized considering whether patients have active disease (or not active), as well as if disease is worsening or stable. Disability in MS is commonly graded on the deterioration of mobility per the Expanded Disability Status Scale (EDSS) an ordinal scale that ranges from 0 to 10, with higher scores indicating greater disability.

Guidelines

In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.² Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS.

A practice guideline recommendation regarding disease-modifying agents for adults with MS from the American Academy of Neurology (2018) states to consider Lemtrada for patients with MS who have highly active disease.⁷

Safety

Lemtrada is available only through a restricted Risk Evaluation Mitigation Strategy (REMS) program called the LEMTRADA REMS Program due to the risks of autoimmunity, infusion reactions, stroke, and malignancies.¹ Use of Lemtrada is contraindicated in patients who have infection with human immunodeficiency virus (HIV) and those with active infection. Progressive multifocal leukoencephalopathy has occurred in a patient with MS who received Lemtrada.

Appendix

Medication	Mode of Administration
Aubagio® (teriflunomide tablets)	Oral
Avonex® (interferon beta-1a intramuscular injection)	Injection (self-administered)
Bafiertam® (monomethyl fumarate delayed-release capsules)	Oral
Betaseron® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Briumvi™ (ublituximab-xiiv intravenous infusion)	Intravenous infusion
Copaxone® (glatiramer acetate subcutaneous injection, generic)	Injection (self-administered)
Extavia® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Gilenya® (fingolimod capsules, generic)	Oral
Glatopa® (glatiramer acetate subcutaneous injection)	Injection (self-administered)
Kesimpta® (ofatumumab subcutaneous injection)	Injection (self-administered)
Lemtrada® (alemtuzumab intravenous infusion)	Intravenous infusion
Mavenclad® (cladribine tablets)	Oral
Mayzent® (siponimod tablets)	Oral
Ocrevus® (ocrelizumab intravenous infusion)	Intravenous infusion
Plegridy® (peginterferon beta-1a subcutaneous or intramuscular injection)	Injection (self-administered)
Ponvory™ (ponesimod tablets)	Oral
Rebif® (interferon beta-1a subcutaneous injection)	Injection (self-administered)
Tascenso ODT™ (fingolimod orally disintegrating tablets)	Oral
Tecfidera® (dimethyl fumarate delayed-release capsules, generic)	Oral
Tyruko® (natalizumab-sztn intravenous infusion)	Intravenous infusion
Tysabri® (natalizumab intravenous infusion)	Intravenous infusion
Vumerity® (diroximel fumarate delayed-release capsules)	Oral
Zeposia® (ozanimod capsules)	Oral

References

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