UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Multiple Sclerosis (Injectable – Other) – Lemtrada Utilization Management Medical Policy
- Lemtrada® (alemtuzumab intravenous infusion – Genzyme)

REVIEW DATE: 07/22/2026

OVERVIEW

Lemtrada, a CD52-directed cytolytic monoclonal antibody, is indicated for the treatment of 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.

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. In addition, practice guidelines for disease-modifying therapies for adults with MS were published by the American Academy of Neurology in 2018.[3] It is noted that many disease-modifying therapies are available and have demonstrated efficacy for the prevention of clinical relapses and new magnetic resonance imaging (MRI)-detected lesions. A lack of response is difficult to define, as most patients with MS are not free of all disease activity. It is recommended that clinicians evaluate various factors, such as clinical relapses, new MRI-detected lesions, or increased disability on examination, over a 1-year period of using a disease-modifying therapy.

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, 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.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lemtrada. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for 30 days, which is an adequate duration for the patient to receive the recommended number of doses. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lemtrada, as well as the monitoring required for adverse

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events and long-term efficacy, approval requires Lemtrada to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lemtrada is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Multiple Sclerosis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for five doses if the patient meets ALL of the following (i, ii, iii, and iv):
     Note: This includes patients who have started but not completed the first course of Lemtrada therapy.
     - **i.** Patient is ≥ 17 years of age; AND
     - **ii.** Patient has a relapsing form of multiple sclerosis; AND
       Note: Examples of relapsing forms of multiple sclerosis include relapsing-remitting disease and active secondary progressive disease.
     - **iii.** Patient meets ONE of the following (a, b, c, or d):
       - **a)** According to the prescriber, the patient has experienced inadequate efficacy or significant intolerance to two disease-modifying agents used for multiple sclerosis; OR
         Note: See Appendix for examples.
       - **b)** According to the prescriber, the patient has experienced inadequate efficacy or significant intolerance to one of Kesimpta (ofatumumab subcutaneous injection), a natalizumab intravenous product (Tysabri, biosimilar), Briumvi (ublituximab-xiiy intravenous infusion), Mavenclad (cladribine tablets), Ocrevus (ocrelizumab intravenous infusion), or Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq subcutaneous injection); OR
       - **c)** Patient has received Lemtrada in the past; OR
       - **d)** According to the prescriber, the patient has highly active or aggressive multiple sclerosis; AND
     - **iv.** The medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
   - **B)** Patient Who Has Completed a Previous Course of Lemtrada Therapy. Approve for three doses if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 17 years of age; AND
     - **ii.** Patient has a relapsing form of multiple sclerosis; AND
       Note: Examples of relapsing forms of multiple sclerosis include relapsing-remitting disease and active secondary progressive disease.
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
         Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability Status Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the Fatigue Symptom and Impact Questionnaire-Relapsing Multiple Sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test

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or 12-Item Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.

b) Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND

iv. At least 12 months have elapsed from the last dose of any prior Lemtrada treatment course; AND

v. The medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Dosing. Approve ONE of the following dosing regimens (A or B):

A) First treatment course is 12 mg/day by intravenous infusion on 5 consecutive days (60 mg total dose); OR

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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lemtrada is not recommended in the following situations:

1. **Clinically Isolated Syndrome.** Lemtrada is not recommended for use in patients with clinically isolated syndrome due to its safety profile.[1]

2. **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.

3. **HIV Infection.** Use of Lemtrada is contraindicated in patients who are infected with HIV because Lemtrada causes prolonged reductions of CD4+ lymphocyte counts.[1]

4. **Non-Relapsing Forms of Multiple Sclerosis.** The efficacy of Lemtrada has not been established in patients with non-relapsing forms of multiple sclerosis.[1]
   Note: An example of a non-relapsing form of multiple sclerosis is primary progressive multiple sclerosis.

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lemtrada® intravenous infusion [prescribing information]. Cambridge, MA: Genzyme; May 2024.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019.
3. 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.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Ocrevus Zunovo was added to the Appendix.	10/09/2024
Selected Revision	**Multiple Sclerosis:** For initial therapy, for the criteria that requires the patient to try one alternative it was added that the patient has experienced inadequate efficacy or significant intolerance (according to the prescriber) to this agent. Also, Ocrevus Zunovo was added to the list of disease-modifying multiple sclerosis drugs that count toward meeting this requirement. The individual listing of Tysabri and Tyruko among these alternatives was changed to state "a natalizumab intravenous product (Tysabri, biosimilar)". Lemtrada was separated from this listing of agents into an individual criterion in which receipt of Lemtrada in the past counts (without requiring inadequate efficacy or significant intolerance [according to the prescriber]).	10/16/2024
Early Annual Revision	Extavia was removed from the Appendix. The name of the policy was changed to add "Injectable – Other".	07/23/2025
Annual Revision	**Multiple Sclerosis:** In Initial Therapy, under the criterion that the patient has highly active or aggressive multiple sclerosis, the specific criteria and documentation requirements were removed. **Appendix:** It was noted that a generic for Mavenclad (cladribine tablets) is now available.	07/22/2026

APPENDIX

Medication	Mode of Administration
Aubagio® (teriflunomide tablets, generic)	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-xiiy intravenous infusion)	Intravenous infusion
Copaxone® (glatiramer acetate subcutaneous injection, generic)	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, generic)	Oral
Mayzent® (siponimod tablets)	Oral
Ocrevus® (ocrelizumab intravenous infusion)	Intravenous infusion
Ocrevus Zunovo® (ocrelizumab and hyaluronidase-ocsq subcutaneous injection)	Subcutaneous injection (not self-administered)
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

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