

Lemtrada® (alemtuzumab)

When requesting Lemtrada® (alemtuzumab), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Lemtrada is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults.

Coverage Guidelines

Multiple Sclerosis (MS)

The individual must meet **all** of the following criteria for initial authorization:

- Has a relapsing form of MS (i.e., relapsing-remitting disease or active secondary progressive disease);
- Is 17 years of age or older;
- Lemtrada is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of MS;
- Meets one of the following:
 - o The patient has experienced inadequate efficacy or significant intolerance to two disease-modifying agents used for MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity, or Zeposia); OR
 - o The patient has experienced inadequate efficacy or significant intolerance to one of the following: Kesimpta, Tysabri, Briumvi, Mavenclad, Ocrevus, or Ocrevus Zunovo; OR
 - o The patient has highly active or aggressive MS defined as one of the following:
 - Demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility or lower levels of ambulation, severe changes in strength or coordination); OR
 - Disabling relapse(s) with suboptimal response to systemic corticosteroids; OR
 - MRI findings suggest highly-active or aggressive disease (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions); OR
 - Manifestations of MS-related cognitive impairment.

The individual must meet **all** of the following criteria for reauthorization:

- Has a relapsing form of MS (i.e., relapsing-remitting disease and active secondary progressive disease);
- Is 17 years of age or older;
- Has completed the first course of Lemtrada treatment (total of 5 doses) (*Note: A patient who has started but not completed the first course of Lemtrada treatment is reviewed under initial authorization criteria.*);
- Lemtrada is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of MS;
- At least 12 months have elapsed from the last dose of any prior Lemtrada treatment course;
- Meets one of the following:
 - o Has experienced a beneficial clinical response when assessed by at least one objective measure (e.g., stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging [MRI], stabilization or reduced worsening on the Expanded Disability State 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 or 12-Item MS Walking Scale, improvement on the Multiple Sclerosis Functional Composite [MSFC] score, and/or attenuation of brain volume loss); OR
 - o Has experienced stabilization, slowed progression, or improvement in at least one symptom (e.g., motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation).

Approval Duration:

Initial: 5 days

Renewal: 3 days

Dosing Recommendations

The recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses:

First treatment course: 12 mg/day on 5 consecutive days.

Second treatment courses: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course.

Following the second treatment course, subsequent treatment courses of 12 mg/day on 3 consecutive days may be administered, as needed, at least 12 months after the last dose of any prior treatment courses.

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. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. No authors listed. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.
7. 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.