

Lemtrada® (alemtuzumab)

When requesting Lemtrada® (alemtuzumab), the individual requiring treatment must be diagnosed with an 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).

Coverage Guidelines

Multiple Sclerosis (MS)

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

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

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

- Has a relapsing form of MS (examples include relapsing-remitting disease and active secondary progressive disease);
- Is 17 years of age or older;
- Lemtrada is being prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis;
- At least 12 months have elapsed from the last dose of any prior Lemtrada treatment course;
- Meets one of the following:
 - Has experienced a beneficial clinical response by at least one objective measure (examples include 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
- Has 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.

Approval Duration:

Initial authorization: approve for 5 days

Reauthorization: approve for 3 days.

Recommended Dosing

First treatment course- 12 mg/day by IV infusion on 5 consecutive days.

Additional treatment courses- 12 mg/day by IV infusion on 3 consecutive days administered 12 months after the last Lemtrada treatment course.

References

1. Lemtrada® injection for intravenous use [prescribing information]. Cambridge, MA: Genzyme Corporation; August 2022.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on January 20, 2023.
3. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
4. 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.
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.