

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

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

- 1) Has a relapsing form of MS (examples include relapsing-remitting disease and active secondary progressive disease); AND
- 2) Is 17 years of age or older; AND
- 3) Lemtrada is being prescribed by or in consultation with a neurologist or a physician that specializes in multiple sclerosis; AND
- 4) The individual meets ONE of the following:
 - a) Has experienced inadequate efficacy or significant intolerance to two disease-modifying agents used for multiple sclerosis (e.g., Avonex, Rebif, Betaseron, Extavia, Copaxone, Plegridy, Gilenya, Glaptopa, glatiramer acetate injection, Aubagio, Tecfidera, Mavenclad, Mayzent, Vumerity, Tysabri, Bafiertam, Zeposia, Kesimpta, or Ocrevus); OR
 - b) 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.

For initial authorization: approve for 5 days.

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

- 1) Has a relapsing form of MS (examples include relapsing-remitting disease and active secondary progressive disease); AND
- 2) Is 17 years of age or older; AND
- 3) Lemtrada is being prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis; AND
- 4) At least 12 months have elapsed from the last dose of any prior Lemtrada treatment course.

For reauthorization: approve x 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; September 2020.
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 November 6, 2020.
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.

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