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

Multiple Sclerosis (MS)

Coverage Guidelines

The individual meets **all** of the following criteria for initial authorization

1) Has a relapsing form of MS; AND
2) 17 years of age or older; AND
3) Is being prescribed by or in consultation with a neurologist or a physician that specializes in multiple sclerosis; AND
4) Had an inadequate response or is unable to tolerate two disease modifying agents (e.g., Avonex, Rebif, Betaseron, Extavia, Copaxone, Plegridy, Gilenya, Glaptopa, glatiramer acetate injection, Aubagio, Tecfidera, Mavenclad, Mayzent, Vumerity, Tysabri, or Ocrevus) used for multiple sclerosis or has highly active or aggressive disease. This is defined as **one** of the following:
    a. Rapidly-advancing deterioration in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination); OR
    b. Disabling relapse with suboptimal response to systemic corticosteroids; OR
    c. MRI findings suggest highly active or aggressive disease (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions); OR
    d. Manifestations of MS related cognitive impairment.

For initial authorization: approve x 5 days

The individual meets **all** of the following criteria for reauthorization

1) Has relapsing form of MS; AND
2) 17 years of age or older; AND
3) 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

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Recommended Dosing

First treatment course- 12mg/day on 5 consecutive days
Additional treatment course- 12mg/day on 3 consecutive days administered 12 months after the last course

References

1. Lemtrada® injection for intravenous use [prescribing information]. Cambridge, MA: Genzyme Corporation; October 2019.
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 7, 2019.
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.
6. Campath® injection for intravenous use [prescribing information]. Cambridge, MA: Genzyme; November 2018.

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