

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

Relapsing forms of multiple sclerosis

Coverage Guidelines

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

- 1) Has a relapsing form of MS (relapsing forms of MS are RRMS, SPMS with relapses, and PRMS); 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 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

For reauthorization (2nd treatment course): approve x 3 days

- 1) 17 years of age or older; AND
- 2) Is being prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis.

Recommended Dosing

First treatment course- 12mg/day on 5 consecutive days

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

References

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4. Campath® injection for intravenous use [prescribing information]. Cambridge, MA: Genzyme Corporation; September 2014.
5. Clinical bulletin. Information for health professionals. Overview of multiple sclerosis. Rosalind Kalb and Nancy Reitman. © 2012 National Multiple Sclerosis Society.
6. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. July 2014. Available at: http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf Accessed October 15, 2018.
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8. 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.
9. The CAMMS223 Trial Investigators. Alemtuzumab vs. interferon beta-1a in early multiple sclerosis. *N Engl J Med*. 2008;359(17):1786-1801.
10. Tuohy O, Costelloe L, Hill-Cawthorne G, et al. Alemtuzumab treatment of multiple sclerosis: long-term safety and efficacy. *J Neurol Neurosurg Psychiatry*. 2015;86:208-215.
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12. Havrdova E, Arnold DL, Cohen JA, et al, on behalf of the CARE-MS I and CAMMS03409 Investigators. Alemtuzumab CARE-MS I 5-year follow-up. *Neurology*. 2017;89:1107-1116.