

Reference number(s) 5316-A

# Jurisdiction Specific Medicare Part B Lemtrada

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lemtrada	alemtuzumab

### **Covered Uses**

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Relapsing forms of multiple sclerosis

#### Limitations of use

Lemtrada is not recommended for use in members with clinically isolated syndrome (CIS) because of its safety profile.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

# **Coverage Criteria**

#### Relapsing Forms of Multiple Sclerosis

Authorization of 1 month may be granted for treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in an adult when any of the following criteria is met:

Member had an inadequate response to two or more drugs indicated for the treatment of MS.

Lemtrada Med B Jurisdiction J (AL GA TN) and M (NC SC VA WV) 5316-A P2025.docx

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 There is a clinical reason as to why the member is unable to use other drugs indicated for the treatment of MS.

# **Dosage and Administration**

The dosage when used for relapsing forms of multiple sclerosis is 12 mg/day infused for 5 consecutive days, then 12 mg/day infused for 3 consecutive days at one interval, one year from the first course of treatment.

For continuing treatment, the last dose of the previous course of treatment received by the member should be at least 12 months prior to the planned date of the next course of Lemtrada.

### References

- Billing and Coding: Instructions for Lemtrada® (alemtuzumab) When Used in the Treatment of Relapsing Multiple Sclerosis (A55310) Version R4. Available at: https://www.cms.gov/medicarecoverage-database/indexes/national-and-local-indexes.aspx. Accessed March 10, 2025.
- 2. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation. May 2024.
- 3. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90(17)777-788.