

Reference number(s)
1843-A

# SPECIALTY GUIDELINE MANAGEMENT

## LEMTRADA (alemtuzumab)

### POLICY

#### I. INDICATIONS

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

##### FDA-Approved Indication

Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

*Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.*

All other indications are considered experimental/investigational and not medically necessary.

#### II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist.

#### III. CRITERIA FOR APPROVAL

##### A. First Course – Relapsing forms of multiple sclerosis

Authorization of 30 days (5 doses) may be granted to members with a diagnosis of a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) who have had an inadequate response to two or more drugs indicated for multiple sclerosis.

##### B. Subsequent Courses – Relapsing forms of multiple sclerosis

Authorization of 30 days (3 doses) may be granted to members with a diagnosis of a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) who have completed at least one previous course of therapy and treatment will start at least 12 months after the last dose of the prior treatment course.

#### IV. OTHER CRITERIA

- A. Members will not use Lemtrada concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

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B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

**V. REFERENCE**

1. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; January 2023.