Reference number(s)
1627-A

Standard Medicare Part B Management 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

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 Indications

Lemtrada is indicated for the treatment of 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 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.

Reference number(s)
1627-A

Coverage Criteria

Multiple Sclerosis

Authorization of 30 days may be granted for treatment of relapsing forms of MS when the member had an inadequate response to two or more drugs for relapsing MS despite adequate duration of treatment or the member has a clinical reason to avoid such treatments.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 30 days may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Lemtrada.
- Lemtrada is being used to treat an indication in the coverage criteria section.
- The member received the last dose of the previous course of treatment at least 12 months prior to the planned date of the next course of Lemtrada.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Lemtrada.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Lemtrada are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.