

# PHARMACY POLICY STATEMENT

## Marketplace

<b>DRUG NAME</b>	<b>Lemtrada (alemtuzumab)</b>
BILLING CODE	J0202
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient hospital
STATUS	Prior Authorization Required

Lemtrada is a CD52-directed cytolytic monoclonal antibody 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, it should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. For the same reason, it is not recommended for use in patients with clinically isolated syndrome (CIS). Lemtrada has a black box warning for autoimmune

For **initial** authorization:

1. Member must be 17 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, a neurologist; AND
3. Chart notes have been provided confirming diagnosis of one of the following types of MS:
  - a) Relapsing-remitting with at least 1 relapse in the past year or
  - b) Active secondary progressive; AND
4. Member has documentation of at least one of the following:
  - a) Inadequate response to two or more drugs indicated for the treatment of MS
  - b) Highly active disease (aggressive or rapidly evolving) in the expert opinion of the prescriber; AND
5. Documentation to show all the following baseline assessments have been or will be completed:
  - a) Complete blood count
  - b) Thyroid function test (e.g., TSH)
  - c) Serum creatinine and urinalysis
  - d) Negative tuberculosis test; AND

Initial course: 12 mg/day IV infusion on 5 consecutive days (60 mg total dose)  
 (QL: 5 vials per 365 days)

For **reauthorization**:

1. Chart notes must document positive clinical response compared to baseline such as fewer relapses or slowed progression of disability; AND
2. Twelve months have elapsed since the last treatment course; AND
3. Treatment plan for the course of therapy is 12 mg/day on 3 consecutive days (36 mg total) (QL: 3 vials per 365 days)

**CareSource considers Lemtrada (alemtuzumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
06/13/2017	New policy for Lemtrada created. Not covered diagnosis added. Trials of two formulary agents required.
12/06/2017	Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer required.
07/08/2022	Transferred to new template. Updated all references. Changed to trial of 2 drugs or highly active disease. Added disqualifiers. Added positive clinical response to renewal criteria. Added dosing information for renewal doses. Added at least 1 relapse in past year to RRMS. Added baseline monitoring.

References:

1. Lemtrada. Prescribing information. Genzyme Corporation; 2022.
2. 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. doi:10.1016/S1474-4422(17)30470-2
3. Rae-Grant A, Day GS, Marrie 7.102 0 4.1 (w 0.964 0e1.4 (on);3.6 ( )0.5 (al)1.4 (.)3.6 )0.6 (i)u BDC 0.001.3 (i)rie o01.3 (i)1