HAP CareSource™

PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	Lemtrada (alemtuzumab)
BENEFIT TYPE	Medical
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 conditions, infusion reactions, stroke, and malignancies. It is only available through a REMS program. Of note, alemtuzumab is also marketed under the brand name Campath for certain cancers.

Lemtrada (alemtuzumab) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

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
6. Member does NOT have any of the following:
   a) Clinically isolated syndrome (CIS)
   b) Human immunodeficiency virus (HIV)
   c) Active infection.
7. **Dosage allowed/Quantity limit:**
   Initial course: 12 mg/day IV infusion on 5 consecutive days (60 mg total dose)
   (QL: 5 vials per 365 days)

If all the above requirements are met, the medication will be approved for 12 months.

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)

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP 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.
06/26/2025	Updated references.

References:

1. Lemtrada. Prescribing information. Genzyme Corporation; 2024.
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 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 [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788
4. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://cdn.sanity.io/files/y936aps5/production/76159995e7f4c6c0c2e6de5c4ba6a5881ab368f7.pdf. Accessed June 26, 2025.
5. McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review [published correction appears in JAMA. 2021 Jun 1;325(21):2211]. *JAMA*. 2021;325(8):765-779. doi:10.1001/jama.2020.26858
6. Riera R, Torloni MR, Martimbianco ALC, Pacheco RL. Alemtuzumab for multiple sclerosis. *Cochrane Database Syst Rev*. 2023;6(6):CD011203. Published 2023 Jun 5. doi:10.1002/14651858.CD011203.pub3

Effective date: 01/01/2026
Revised date: 06/26/2025