**RX.PA.047.MPC Lemtrada (alemtuzumab)**

The purpose of this policy is to define the prior authorization process for Lemtrada® (alemtuzumab).

Lemtrada® (alemtuzumab) is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Lemtrada® (alemtuzumab) generally should be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

**PROCEDURE**

**A. Initial Authorization Criteria:**

**1. All requests must meet the following criteria:**

- Member must be 18 years of age or older
- Member must have a diagnosis of a relapsing form of multiple sclerosis (MS)
    - Includes relapsing-remitting disease and active secondary progressive disease
- According to the prescriber, the patient has highly-active or aggressive multiple sclerosis by meeting one of the following [(1), (2), (3), or (4)]:
    - (1) Patient has demonstrated rapidly advancing deterioration(s) in physical functioning. Member must present at least two examples below. [documentation required]; OR

      Note: Examples include loss of mobility/or lower levels of ambulation and severe changes in strength or coordination.
    - (2) Disabling relapse(s) with suboptimal response despite two trials of systemic corticosteroids. Member had ≥ 2 relapses within the past year. [documentation required]; OR
    - (3) Magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis. Member must present two of the examples below and have ≥ 10 lesions [documentation required]; OR

      Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions.
    - (4) Manifestations of multiple sclerosis-related cognitive impairment involving significant memory deficits and visuospatial perception. [documentation required]; AND
- Must be prescribed by a neurologist or in consultation with a neurologist
- Must not be HIV positive

- Prescriber and member must be enrolled in the LEMTRADA REMS program
- Must have recent (within 6 months) assessments of all of the following:
  - Complete blood count (CBC)
  - Serum creatinine level
  - Urinalysis with urine cell counts
  - Thyroid function test (e.g. TSH)
  - Skin exam
- Must not be used in combination with another multiple sclerosis disease modifying agent
- Must have documented inadequate treatment response (trial of 3 months) or intolerance to at least two of the following multiple sclerosis treatments:
  - Glatopa® (glatiramer acetate)
  - Tecfidera® (dimethyl fumarate)
  - Extavia® (interferon β-1b)
  - Rebif® (interferon β-1a)
  - Must have documented inadequate treatment response (trial of 3 months) or intolerance to Ocrevus

**B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

**C. Lemtrada will be considered investigational or experimental for any other use and will not be covered.**

**D. <u>Reauthorization Criteria:</u>**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for an additional course of treatment. Authorization may be granted for an additional course of treatment, consisting of 3 doses given on 3 consecutive days, at least 1 year after previous 5-dose course, based upon the following:

MPC Renewal:

- Documentation from the prescriber showing that the member has improved/stabilized based on the prescriber's assessment
- Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation
- Documentation that all of the following have been evaluated since last course of Lemtrada:

  - Complete blood count (CBC)
  - Serum creatinine level
  - Urinalysis with urine cell counts
  - Thyroid function test (e.g. TSH)
  - Skin exam
- Must be prescribed by a neurologist or in consultation with a neurologist
- Must not be HIV positive
- At least 12 months has elapsed from the last dose of any prior Lemtrada treatment course

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Therapy)
- Provider has a documented clinical response of the member's condition which has stabilized or improved compared to baseline.

**Limitations:**

| Length of Authorization (if above criteria met) | |
|---|---|
| Initial Authorization | 1 treatment course (5 doses administered on 5 consecutive days) |
| Reauthorization | 1 treatment course (3 doses administered on 3 consecutive days) |

**Codes:**

| Code | Description |
|---|---|
| J0202 | Injection, alemtuzumab, 1 mg |

**REFERENCES**

1. Lemtrada [package insert]. Cambridge, MA: Gemzyme Corporation; August 2021.

## REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| *Annual Review* | *02/2026* |
| *Annual Review* | *02/2025* |
| *Annual Review*<br>*Change in Non-MPC renewal to renewal from previous insurer* | *02/2024* |
| *Annual Review* | *02/2023* |
| *Selected Revision*<br>*Expanded initial criteria to include clinical documentation*<br>*Addition of MPC vs Non-MPC Renewal Criteria* | *10/2022* |
| *Annual Review* | *02/2022* |
| *Addition of dosing requirements* | *12/2021* |
| *New Policy* | *09/2021* |