

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
- Must be prescribed by a neurologist or in consultation with a neurologist
- Must not be HIV positive
- 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:
 - Aubagio[®] (teriflunomide)
 - Copaxone[®] (glatiramer acetate)
 - Tecfidera[®] (dimethyl fumarate)
 - Extavia[®] (interferon β -1b)

- Rebif® (interferon β -1a)

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. Reauthorization Criteria:

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:

- Documentation from the prescriber showing that the member has improved/stabilized based on the prescriber's assessment
- 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

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
<i>Annual Review</i>	<i>02/2022</i>
<i>Addition of dosing requirements</i>	<i>12/2021</i>
<i>New Policy</i>	<i>09/2021</i>