Clinical Policy: Alemtuzumab (Lemtrada)
Reference Number: ERX.SPMN.162
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that alemtuzumab (Lemtrada™) is medically necessary for the following indications:

I. Initial Approval Criteria
   A. Multiple Sclerosis (must meet all):
      1. Prescribed by or in consultation with a neurologist;
      2. Age ≥ 18 years;
      3. Diagnosis of relapsing-remitting multiple sclerosis (RRMS) established by MRI;
      4. Member has a contraindication to or failed (a or b):
         a. Betaseron or Rebif AND at least one of the following agents: glatiramer acetate (Copaxone, Glatopa), Tecfidera, Gilenya, or Aubagio;
         b. Any 2 of the following agents: glatiramer acetate (Copaxone, Glatopa), Tecfidera, Gilenya, or Aubagio;
      5. Prescribed dose does not exceed 60 mg total per single treatment course;
      6. Member will not use other disease modifying therapies for MS concurrently.

   Approval duration: 12 months (1st treatment course administered over 5 days)

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval
   A. Multiple Sclerosis (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Responding positively to therapy;
      3. Prescribed dose does not exceed 36 mg total per single treatment course;
      4. It has been at least 12 months since completion of the first treatment course;
      5. Member has not completed two treatment courses of Lemtrada;
      6. Member will not use other disease modifying therapies for MS concurrently.

   Approval duration: 12 months (2nd treatment course administered over 3 days)

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.
Background

**Description/Mechanism of Action:**
Lemtrada is a recombinant humanized IgG1 kappa monoclonal antibody. The precise mechanism by which it exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes, and macrophages. Following cell surface binding to T and B lymphocytes, Lemtrada results in antibody-dependent cellular cytology and complement-mediated lysis.

**Formulations:**
Lemtrada is a sterile, clear and colorless to slightly yellow solution for infusion containing no antimicrobial preservatives supplied as single-use vials.

**FDA Approved Indication(s):**
Lemtrada is a monoclonal antibody/intravenous infusion indicated for:
- Treatment of patients with relapsing forms of multiple sclerosis.

**Limitations of use:**
- 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.

**Appendices**

**Appendix A: Abbreviation Key**
MRI: magnetic resonance imaging
MS: multiple sclerosis
RRMS: relapsing-remitting multiple sclerosis

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J0202</td>
<td>Injection, alemtuzumab, 1 mg</td>
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**Reviews, Revisions, and Approvals**

Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Removed all safety criteria, added max dosing, clarified monotherapy restriction, modified trial/failure criteria to require trial/failure of 2 agents from different classes, and updated continuation (second treatment course) criteria.

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<tr>
<th>Date</th>
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<td>08/16</td>
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References


Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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