Clinical Policy: Alemtuzumab (Lemtrada)
Reference Number: CP.CPA.325
Effective Date: 06.01.18
Last Review Date: 05.19
Line of Business: Commercial

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

Description
Alemtuzumab (Lemtrada®) is a CD52-directed cytolytic monoclonal antibody.

FDA Approved Indication(s)
Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Limitation(s) 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Lemtrada is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Multiple Sclerosis (must meet all):
      1. Diagnosis of relapsing-remitting MS;
      2. Prescribed by or in consultation with a neurologist;
      3. Age ≥ 18 years;
      4. Failure of two of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: Aubagio®, Tecfidera®, Gilenya™, Avonex®, Betaseron®, Plegridy®, glatiramer, Copaxone®, Glatopa®, or Rebif®;
         *Prior authorization is required for all disease modifying therapies for MS
      5. Lemtrada is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
      6. Dose does not exceed:
         a. First treatment course: 12 mg per day for 5 consecutive days (60 mg total);
         b. Second or subsequent treatment courses: 12 mg per day for 3 consecutive days (36 mg total).

   Approval duration: 6 months or to the member’s renewal date, whichever is longer
B. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy
A. Multiple Sclerosis (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Lemtrada is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
4. It has been at least 12 months since completion of the prior treatment course;
5. Dose does not exceed 12 mg per day for 3 consecutive days (36 mg total per treatment course).

Approval duration: 6 months or to the member’s renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 or evidence of coverage documents;
B. Primary progressive MS.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avonex®, Rebif® (interferon beta-1a)</td>
<td>Avonex: 30 mcg IM Q week  Rebif: 22 mcg or 44 mcg SC TIW</td>
<td>Avonex: 30 mcg/week  Rebif: 44 mcg TIW</td>
</tr>
<tr>
<td>Plegrify®, (peginterferon beta-1a)</td>
<td>125 mcg SC Q2 weeks</td>
<td>125 mcg/2 weeks</td>
</tr>
</tbody>
</table>
### Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): infection with human immunodeficiency virus
- Boxed warning(s): autoimmunity, infusion reactions, stroke, and malignancies

### Appendix D: General Information
- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocrelizumab (Ocrevus™).
- Lemtrada is available only through a restricted program under a REMS called the Lemtrada REMS Program because of the risks of autoimmunity, infusion reactions, and malignancies.

### V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapsing MS</td>
<td>IV infusion for 2 or more treatment courses:</td>
<td>See regimen</td>
</tr>
<tr>
<td></td>
<td>• First course: 12 mg/day on 5 consecutive days</td>
<td></td>
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<tr>
<td></td>
<td>• Second course: 12 mg/day on 3 consecutive days 12 months after first course</td>
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<tr>
<td></td>
<td>• Subsequent courses as needed: 12 mg/day on 3 consecutive days 12 months after any prior course</td>
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</tr>
</tbody>
</table>

### VI. Product Availability
- Single-use vial: 12 mg/1.2 mL

### VII. References

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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0202</td>
<td>Injection, alemtuzumab, 1 mg</td>
<td>06.17</td>
<td>11.17</td>
</tr>
</tbody>
</table>

Reviews, Revisions, and Approvals

- Converted to new template. Minor changes to verbiage and grammar. References updated. 06.17 11.17
- Policy created: no significant changes from previously approved corporate policy; split from CP.CPA.206 Multiple Sclerosis; age added; removed COC statement from re-auth; added requirement for no concurrent use with other MS therapies; references reviewed and updated. 01.05.18 05.18
- 2Q 2019 annual review: added glatiramer as a step-through option; for re-auth, added that at least 12 months should elapse between treatment courses; references reviewed and updated. 02.04.19 05.19

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and
limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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