

## **Clinical Policy: Alemtuzumab (Lemtrada)**

Reference Number: CP.CPA.325

Effective Date: 06.01.18

Last Review Date: 05.18

Line of Business: Commercial

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Alemtuzumab (Lemtrada<sup>®</sup>) 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<sup>®</sup> 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  $\geq$  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, Copaxone, Glatopa, or Rebif;
5. Lemtrada is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix C*);
6. Dose does not exceed 12 mg/day for 5 consecutive days (60 mg total).

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

##### **B. Other diagnoses/indications**

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### **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 C*);
4. Dose does not exceed 12 mg/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 (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 CP.CPA.09 for commercial if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
Avonex <sup>®</sup> , Rebif <sup>®</sup> (interferon beta-1a)	Avonex: 30 mcg IM Q week Rebif: 22 mcg or 44 mcg SC TIW	Avonex: 30 mcg/week Rebif: 44 mcg TIW
Plegridy <sup>®</sup> (peginterferon beta-1a)	125 mcg SC Q2 weeks	125 mcg/2 weeks
Betaseron <sup>®</sup> , Extavia <sup>®</sup> (interferon beta-1b)	250 mcg SC QOD	250 mg QOD
glatiramer acetate (Copaxone <sup>®</sup> , Glatopa <sup>®</sup> )	Copaxone: 20 mg SC QD or 40 mg SC TIW Glatopa: 20 mg SC QD	Copaxone: 20 mg/day or 40 mg TIW Glatopa: 20 mg/day
Aubagio <sup>®</sup> (teriflunomide)	7 mg or 14 mg PO QD	14 mg/day
Gilenya <sup>™</sup> (fingolimod)	0.5 mg PO QD	0.5 mg/day
Tecfidera <sup>®</sup> (dimethyl fumarate)	120 mg PO BID for 7 days, followed by 240 mg PO BID	480 mg/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: General Information*

- Disease-modifying therapies for MS are: daclizumab (Zinbryta<sup>®</sup>), glatiramer acetate (Copaxone<sup>®</sup>, Glatopa<sup>®</sup>), interferon beta-1a (Avonex<sup>®</sup>, Rebif<sup>®</sup>), interferon beta-1b (Betaseron<sup>®</sup>, Extavia<sup>®</sup>), peginterferon beta-1a (Plegridy<sup>®</sup>), dimethyl fumarate (Tecfidera<sup>®</sup>), fingolimod (Gilenya<sup>™</sup>), teriflunomide (Aubagio<sup>®</sup>), alemtuzumab (Lemtrada<sup>®</sup>), mitoxantrone (Novantrone<sup>®</sup>), natalizumab (Tysabri<sup>®</sup>), and ocrelizumab (Ocrevus<sup>™</sup>).
- 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**

Indication	Dosing Regimen	Maximum Dose
Relapsing MS	IV infusion for 2 treatment courses: <ul style="list-style-type: none"> <li>• First course: 12 mg/day on 5 consecutive days</li> <li>• Second course: 12 mg/day on 3 consecutive days 12 months after first course</li> </ul>	See regimen

**VI. Product Availability**

Single-use vial: 12 mg/1.2 mL

**VII. References**

1. Lemtrada Prescribing Information. Cambridge, MA: Genzyme Corporation; December 2017. Available at <http://www.lemtrada.com>. Accessed January 5, 2018.
2. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. March 2017. Accessed January 5, 2018.

**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.

HCPCS Codes	Description
J0202	Injection, alemtuzumab, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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

**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.

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