

Clinical Policy: Alemtuzumab (Lemtrada)

Reference Number: CP.PHAR.243

Effective Date: 08.01.16

Last Review Date: 05.19

Line of Business: Medicaid, HIM-Medical Benefit

[Coding Implications](#)

[Revision Log](#)

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 \geq 18 years;
4. Failure of one of the following (a or b) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Tecfidera[®] or Gilenya[™] and any of the following: an interferon-beta agent (Avonex[®] and Plegridy[®] are preferred agents) or glatiramer (Glatopa[®] 20 mg and Copaxone[®] 40 mg are preferred agents);
 - b. Tecfidera and Gilenya;

**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: 12 months

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.PMN.53 for Medicaid and HIM-Medical Benefit.

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: 12 months

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.PMN.53 for Medicaid and HIM-Medical Benefit.

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 – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid and HIM-Medical Benefit 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Avonex [®] , Rebif [®] (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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Plegridy [®] (peginterferon beta-1a)	125 mcg SC Q2 weeks	125 mcg/2 weeks
Betaseron [®] , Extavia [®] (interferon beta-1b)	250 mcg SC QOD	250 mg QOD
glatiramer acetate (Copaxone [®] , Glatopa [®])	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
Gilenya [™] (fingolimod)	0.5 mg PO QD	0.5 mg/day
Tecfidera [®] (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[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

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

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

VI. Product Availability

Single-use vial: 12 mg/1.2 mL

VII. References

1. Lemtrada Prescribing Information. Cambridge, MA: Genzyme Corporation; January 2019. Available at <http://www.lemtrada.com>. Accessed February 4, 2019.

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 February 4, 2019.
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018; 90(17): 777-788. Full guideline available at: <https://www.aan.com/Guidelines/home/GetGuidelineContent/904>.

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
Policy split from CP.PHAR.18 MS Treatments. Criteria: added max dosing, clarified monotherapy restriction, updated continuation criteria. Added information about REMS program. Age requirement added; requirement for the trial and failure of at least 2 preferred regimens from different classes added.	08.16	08.16
Removed MRI requirement. Updated preferencing to require at least one of the highly effective DMTs on formulary (Tecfidera or Gilenya). Removed reasons to discontinue.	07.17	08.17
2Q 2018 annual review: no significant changes; removed HIV contraindication; added HIM; references reviewed and updated.	01.05.18	05.18
2Q 2019 annual review: for re-auth, removed restriction for a total of 2 treatment courses per updated FDA labeling which allows for 2 or more 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

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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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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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