Clinical Policy: Alemtuzumab (Lemtrada)

Reference Number: PA.CP.PHAR.243
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for alemtuzumab (Lemtrada™).

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
It is the policy of Pennsylvania Health and Wellness® that Lemtrada is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of a relapsing form of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 17 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;
5. Member will not use other disease modifying therapies for MS concurrently;
6. Dose does not exceed 12 mg/day for 5 consecutive days (60 mg total).

Approval duration: 12 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions);
3. Member is not using other disease modifying therapies for MS concurrently;
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. Dose does not exceed 12 mg/day for 3 consecutive days (36 mg total).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - 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 cytolysis 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.

Safety Information:
Lemtrada is available only through a restricted distribution program called the Lemtrada REMS Program because of the risks of autoimmunity, infusion reactions, and malignancies.

Appendices
Appendix A: Abbreviation Key
FDA: Food and Drug Administration
MS: 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.

HCPCS Codes	Description
J0202	Injection, alemtuzumab, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed HIV contraindication; references reviewed and updated	01.05.18	

References

1. Lemtrada Prescribing Information. Cambridge, MA: Genzyme Corporation; July 2016. 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. July 2016. Accessed January 5, 2018.