Lemtrada® (alemtuzumab)

Indications:

"Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). 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."[1]

Dosage Form/Strength:

Injection: 12mg/1.2mL (10mg/mL) in a single-use vial.

Criteria for Approval: [1, 2]

1. Submitted JCode of J0202; **AND**
2. Diagnosis of relapsing remitting Multiple Sclerosis (MS); **AND**
3. Patient has had an inadequate response to at least 2 medications FDA-indicated for the treatment of MS; **AND**
4. Compliance with the requirements of the Lemtrada REMS program:
    a. Prescriber has been certified with the program by enrolling and completing training.
    b. Patient is enrolled in the program and complies with ongoing monitoring requirements.
    c. Dispensing pharmacy is certified with the program and only dispenses to certified healthcare facilities that are authorized to receive Lemtrada.
    d. Healthcare facility is enrolled in the program and verifies that patients are authorized before infusing Lemtrada.
    e. Healthcare facility has on-site access to equipment and personnel trained to manage infusion reactions.
    f. Patient has baseline lab tests deemed as acceptable under the REMS program requirements (results are submitted with the prior authorization request); **AND**
5. The provider administering Lemtrada must be enrolled with Alaska Medicaid as a Health Professional Group or Medical provider (physician or APRN); **AND**
6. Lemtrada is not being administered under the Alaska Medicaid Home Infusion Therapy program; **AND**
7. Patient will not be receiving Lemtrada in combination with another MS disease modifying agent (e.g., Avonex®, Betaseron®, Extavia®, Plegridy®, Rebif® [interferon beta preparations], Copaxone®, Glatopa™ [glatiramer acetate], Tecfidera® [dimethyl fumarate]); **AND**
8. Patient has had negative tests for both tuberculosis and Human Immunodeficiency Virus (HIV) infection prior to treatment.

Criteria for Reauthorization Approval:

1. Patient meets all of the criteria for the initial authorization; **AND**
2. There is documented evidence of a positive clinical response to Lemtrada therapy; **AND**

3. Patient's current lab tests are deemed as acceptable under the REMS program requirements for continuation of therapy. Documentation of lab tests must be submitted.

Criteria for Denial:

1. Any diagnosis other than relapsing remitting multiple sclerosis; **OR**
2. Concurrent HIV infection; **OR**
3. Patient has not previously had an inadequate response to at least 2 medications FDA-indicated for the treatment of MS; **OR**
4. The patient, prescriber, dispensing pharmacy, and facility administering Lemtrada have not all been approved by the Lemtrada REMS program requirements; **OR**
5. Patient will be receiving Lemtrada in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, dimethyl fumarate) ; **OR**
6. Patient has not been tested for tuberculosis, or the patient tested positive for tuberculosis infection; **OR**
7. The provider administering Lemtrada is not enrolled with Alaska Medicaid as a Health Professional Group or Medical provider (physician or APRN) ; **OR**
8. Lemtrada will be administered under the Alaska Medicaid Home Infusion Therapy program.

Length of Authorization – Initial coverage:

- Initial coverage may be authorized for up to 1 year.
- Reauthorization may be approved for up to 1 year.

Quantity Limit:

- Initial authorization 5 vials (6mL)
- Subsequent reauthorizations 3 vials (3.6mL)

Mechanism of Action:

"The precise mechanism by which alemtuzumab 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, alemtuzumab results in antibody-dependent cellular cytolysis and complement-mediated lysis." [1]

References / Footnotes:

[1]Lemtrada® package insert: Genzyme Corporation. Cambridge, MA. November 2014. http://products.sanofi.us/lemtrada/lemtrada.pdf. Accessed 3/3/2016.
[2] Lemtrada REMS Program. Genzyme. https://www.lemtradarems.com/ . Accessed 3/2/2016.
[3] U.S. Food and Drug Administration (FDA). Approved risk evaluation and mitigation strategies (REMS). Available at: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. Accessed 3/3/2016.