Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 125.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Lemtrada (alemtuzumab)

I. Policy:
Lemtrada (alemtuzumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Lemtrada (alemtuzumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Lemtrada (alemtuzumab) 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 be generally reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Lemtrada (alemtuzumab) will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of diagnosis of relapsing form of multiple sclerosis **AND**
- Medical record documentation of age 17 or older **AND**
- Medical record documentation that patient is using Lemtrada as monotherapy **AND**
- Medical record documentation that Lemtrada is prescribed by a neurologist **AND**
- Medical record documentation that patient is receiving pre-medication with high dose corticosteroids and herpetic prophylaxis during therapy **AND**
- No medical record documentation of active/chronic infection **AND**
- Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immunosuppressive, or immune modulating therapies **AND**
- Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy **AND**
- Medical record documentation that patient is up to date on all required vaccinations **AND**
- Documentation of positive antibody for varicella zoster (either physician documented diagnosis or vaccination history) **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three formulary alternatives, one of which must by Tysabri.

Quantity Limits: 5 doses (60mg) for initial authorization, 3 doses (36mg) for reauthorization

AUTHORIZATION DURATION:
Initial authorization will be given for 5 doses and a duration of 1 year. Reauthorizations will be given for a duration of 12 months with a quantity limit of 3 doses per 12-month duration and will require:

- Medical record documentation that Lemtrada is being used as monotherapy **AND**
- Medical record documentation that patient has not started therapy with another DMT since initial 5 doses **AND**
- Medical record documentation that the 3 doses are being administered 1 year after initial 5 doses or if subsequent re-authorizations documentation that at least 12 months have passed since the last dose of any prior treatment course **AND**
- Medical record documentation that patient is receiving pre-medication with high dose corticosteroids and herpetic prophylaxis during therapy **AND**
- No medical record documentation of active/chronic infection **AND**
- Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immunosuppressive, or immune modulating therapies **AND**
- Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy **AND**
- Medical record documentation that patient is up to date on all required vaccinations

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Lemtrada (alemtuzumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of diagnosis of relapsing form of multiple sclerosis **AND**
- Medical record documentation of age 17 or older **AND**
- Medical record documentation that patient is using Lemtrada as monotherapy **AND**
- Medical record documentation that Lemtrada is prescribed by a neurologist **AND**
- Medical record documentation that patient is receiving pre-medication with high dose corticosteroids and herpetic prophylaxis during therapy **AND**

- No medical record documentation of active/chronic infection **AND**
- Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immunosuppressive, or immune modulating therapies **AND**
- Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy **AND**
- Medical record documentation that patient is up to date on all required vaccinations **AND**
- Documentation of positive antibody for varicella zoster (either physician documented diagnosis or vaccination history) **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to two formulary alternatives

Quantity Limits: 5 doses (60mg) for initial authorization, 3 doses (36mg) for reauthorization

AUTHORIZATION DURATION:
Initial authorization will be given for 5 doses and a duration of 1 year. Reauthorizations will be given for a duration of 12 months with a quantity limit of 3 doses per 12-month duration and will require:

- Medical record documentation that Lemtrada is being used as monotherapy **AND**
- Medical record documentation that patient has not started therapy with another DMT since initial 5 doses **AND**
- Medical record documentation that the 3 doses are being administered 1 year after initial 5 doses or if subsequent re-authorizations documentation that at least 12 months have passed since the last dose of any prior treatment course **AND**
- Medical record documentation that patient is receiving pre-medication w/ high dose corticosteroids and herpetic prophylaxis during therapy **AND**
- No medical record documentation of active/chronic infection **AND**
- Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immunosuppressive, or immune modulating therapies **AND**
- Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy **AND**
- Medical record documentation that patient is up to date on all required vaccinations

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Lemtrada [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/24/15

Revised: 9/20/16 (revised criteria), 7/9/19 (auth duration per PARP), 1/16/23 (LOB carve out), 12/30/23 (references added)

Reviewed: 3/31/2016, 7/31/17, 7/10/18, 5/31/19, 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23