Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Lemtrada (alemtuzumab)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2015 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Lemtrada (alemtuzumab).

Lemtrada (alemtuzumab) is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of alemtuzumab (Lemtrada) generally should be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Lemtrada (alemtuzumab), is subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY
Requests for Lemtrada are subject to the preferred medical drug list program. This program applies to the multiple sclerosis products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Multiple sclerosis (MS) products

	Product(s)
Preferred	• Tysabri **(natalizumab)**
Non-Preferred	• Lemtrada **(alemtuzumab)**

Requests for Lemtrada must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA *(Use for Lemtrada Requests Only)*

This program applies to members requesting treatment for an indication that is both FDA-approved for the preferred product and the non-preferred product.

Coverage for the non-preferred product is provided when any of the following criteria is met:

A. Member is currently receiving treatment with the non-preferred product, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
B. Member has experienced a documented inadequate response and/or intolerable adverse event to treatment with the preferred product.

C. Member has a documented contraindication to therapy with the preferred product or any of its components.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet ALL of the clinical criteria listed below:

- Must be prescribed by a neurologist
- Must be age 18 years or older
- Must have a diagnosis of a relapsing form of MS
- Must previously have had an inadequate response or intolerance to glatiramer (Copaxone1) and interferon beta-1a (Avonex1)
- Must not be HIV positive
- Must have a negative tuberculosis skin test such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test rsuch as QuantiFERON1 -TB Gold In-Tube test (QFT-GIT) or T-SPOT1 .TB test (T-Spot)]
- Must demonstrate immunity to varicella zoster virus (VZV) by VZV antibody serology. Documentation is required.
- Demonstrated immunity is NOT required for patients who have been vaccinated against VZV. Chart documentation, including date of VZV vaccination, is required.
- Must have recent (within 6 months) assessments of all of the following:
    - Complete blood count (CBC)
    - Serum creatinine level
    - Urinalysis with urine cell counts
    - Thyroid function test (e.g. TSH)
    - Skin exam
- Must not be on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies
- Must have previously had an inadequate response or intolerance to two of the following multiple sclerosis therapies: glatiramer acetate (Copaxone®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya®), natalizumab (Tysabri®), or teriflunomide (Aubagio®)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for an additional course of treatment. Authorization may be granted for an additional course of treatment, consisting of 3 doses given on 3 consecutive days, at least 1 year after previous 5-dose course, based upon the following:

- Documentation from the prescriber showing that the member has improved/stabilized based on the prescriber s assessment
- Documentation that all of the following have been evaluated since last course of alemtuzumab (Lemtrada):
    - Complete blood count (CBC)
    - Serum creatinine level
    - Urinalysis with urine cell counts
    - Thyroid function test (e.g. TSH)
    - Skin exam

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	1 course of therapy (5 doses given on 5 consecutive days)
Reauthorization	1 course of therapy (3 doses given on 3 consecutive days)

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Lemtrada rprescribing information]. Cambridge, MA: Genzyme Corporation; November 2014
2. Cohen JA, Coles AJ, Arnold C, et al. Alemtuzumab versus interferon beta 1a as first line treatment for patients with relapsing-remitting multiple sclerosis: a randomized controlled phase 3 trial. Lancet 2012:380;1819-28
3. Coles AJ, Twyman CL, Arnold DL, et al. Alemtuzumab for patients with relapsing multiple sclerosis after disease modifying therapy: a randomized controlled phase 3 trial. Lancet 2012;380:1829-39

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 01/18*
Preferred Product Update (effective 4/1/18)	*02/18*