

<b>Policy Title:</b>	Lemtrada (alemtuzumab) (Intravenous)		
<b>Policy Number:</b>	<i>To be determined</i>	<b>Department:</b>	PHA
<b>Effective Date:</b>	07/01/2019		
<b>Review Date:</b>	04/10/2019		
<b>Revision Date:</b>	04/10/2019		

**Purpose:** To support safe, effective and appropriate use of Lemtrada (alemtuzumab) in treatment of Multiple Sclerosis (MS).

**Scope:** Medicaid, Exchange, Integrity

**Policy Statement:**

Lemtrada (alemtuzumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Lemtrada (alemtuzumab) will be reviewed prospectively via the prior authorization process based on criteria below.

***Initial Criteria Coverage for Medicaid and Exchange:***

- Patient has been diagnosed with a relapsing form of multiple sclerosis (MS);
- Patient has had an inadequate response to two or more drugs indicated for MS;
- Patient should have documented failure, intolerance or contraindication to therapy with Tysabri (natalizumab);
- Dose does not exceed 12 billable units per dose or (1 dose daily for 5 days( 60 billable units), followed by 1 dose daily for 3 days (36 billable units, one year later).

***Initial Criteria Coverage for Integrity ONLY:***

- Patient has been diagnosed with a relapsing form of multiple sclerosis (MS);
- Patient has had an inadequate response to two or more drugs indicated for MS;
- Dose does not exceed 12 billable units per dose or (1 dose daily for 5 days( 60 billable units), followed by 1 dose daily for 3 days (36 billable units, one year later).

***Renewal Criteria:***

- Patient is tolerating treatment with Lemtrada (alemtuzumab), excluding when Lemtrada (alemtuzumab) is obtained as samples or via manufacturer's patient assistance programs who have completed at least one course of therapy.

**Coverage durations:**

- Initial coverage: 5 doses (60 billable units ) for 30 days
- Renewal coverage: 3 doses (36 billable units) for 30days

**Investigational Use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:** Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis(specify substance or drug), initial, up to 1 hour
96366	Intravenous infusion ,Each additional hour
J0202	Injection, alemtuzumab, 1mg

**References:**

1. Lemtrada prescribing information. Cambridge, MA: Genzyme Corporation, 2019 January.

2. Tuohy O, Costelloe L, Hill-Cawthorne G, Bjornson I, Harding K, Robertson M, May K, Button T, Azzopardi L, Kousin-Ezewu O, Fahey MT, Jones J, Compston DA, Coles A. Alemtuzumab treatment of multiple sclerosis: long term safety and efficacy. *J Neurol Neurosurg Psychiatry*. 2015 Feb;86:208-1