Policy Title:	Lemtrada (alemtuzumab) (Intravenous)		
Policy Number:	000577	**Department:**	PHA
Effective Date:	09/12/2018		
Review Date:			
Revision Date:			

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:

- Patient has been diagnosed with a relapsing form of multiple sclerosis.; and
- Confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); and
- Must be used as single agent therapy; and
- Must be prescribed by a neurologist; and
- Patient should have had an inadequate response to an adequate trial of two or more drugs indicated for the treatment of relapsing MS ; and
- 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)

Continuation of therapy:

- Coverage cannot be renewed

Coverage durations:

- Initial coverage: 8 doses to be administered within a 2 year period

Investigational use: Lemtrada (alemtuzumab) is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Additional information:

Indications:

- Lemtrada (alemtuzumab) is FDA approved for 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.

***Dosing*:**

- The recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses:
  - First Treatment Course: 12 mg/day on 5 consecutive days (60 mg total dose)
  - Second Treatment Course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course.

Administration:

- Administer Lemtrada in a setting in which equipment and personnel can appropriately manage anaphylaxis or serious infusion reactions.

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, 2017 December.
2. TuohyO, 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 Psychiarty*. 2015 Feb;86:208-15