Policy Title:	Lemtrada (alemtuzumab) (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/10/2019, 9/18/2019, 12/20/2019, 1/22/20, 6/10/2021, 6/16/2022		
Revision Date:	04/10/2019, 9/18/2019, 12/20/2019, 1/22/20, 6/10/2021		

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

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

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

- Patient has been diagnosed with a relapsing form of multiple sclerosis (MS); AND
- Patient has had an inadequate response to two or more drugs indicated for MS; AND
- Patient should have documented failure, intolerance or contraindication to therapy with Tysabri (natalizumab); AND
- Dose does not exceed 12 billable units per dose, followed by 1 dose daily for 3 days;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- Patient is tolerating treatment with Lemtrada (alemtuzumab); AND
- Patient has experienced disease improvement or slowing of disease worsening (e.g., no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy; AND
- Patient has not received a dose of Lemtrada within the last 12 months.

Coverage durations:

- Initial coverage: 5 doses for 30 days
- Renewal coverage: 3 doses for 30 days

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dose	Maximum units (1 billable unit = 1 mg)
All Indications	First course: 12 mg/day on 5 consecutive days (60 mg total dose) Second course: 12 mg/day on 3 consecutive days (36 mg total dose), administered 12 months after the first treatment course. Subsequent courses: 12 mg/day on 3 consecutive days (36 mg total dose) administered , as needed, at least 12 months after the last dose of any prior treatment course	First Course: 60 billable units (1 dose daily x 5 days) during the first 12 months Second/Subsequent Courses: 36 billable units (1 dose daily x 3 days) every 12 months thereafter

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
J0202	Injection, alemtuzumab, 1mg

References:

1. Lemtrada prescribing information. Cambridge, MA: Genzyme Corporation, January 2022.
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

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