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, 7/13/2023, 12/07/2023, 01/10/2024		

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.

Summary of Evidence:

Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults. Clinical trials evaluating the efficacy and safety of Lemtrada have demonstrated significant reductions in the annualized relapse rate, slowing of disability progression, and decreased MRI lesion activity compared to placebo or active comparator groups. Because of its safety profile, the use of Lemtrada is generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Initial Criteria

- Patient has been diagnosed with a relapsing form of multiple sclerosis (MS) [i.e., relapsing-remitting disease (RRMS) or active secondary progressive MS (SPMS)]; AND
- Confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); AND
- Lemtrada is prescribed by or in consultation with a neurologist; AND
- Must be used as single agent therapy; AND
- MMP & Commercial members must have a documented failure, intolerance, or contraindication to with Ocrevus (ocrelizumab) and Tysabri (natalizumab); OR
- Medicaid members must have an inadequate response, intolerance, or contraindication to Tysabri (natalizumab) and one more drug indicated for MS

* 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 365 days
- Renewal coverage: 3 doses for 365 days

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale: Lemtrada was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Lemtrada according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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	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

	12 months after the last dose of any prior treatment course	

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, May 2023. Accessed November 2023.
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;86:208-1