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

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:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum units (1 billable unit = 1 mg)</th>
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</thead>
<tbody>
<tr>
<td>All Indications</td>
<td>First course: 12 mg/day on 5 consecutive days (60 mg total dose)</td>
<td>First Course: 60 billable units (1 dose daily x 5 days) during the first 12 months</td>
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<tr>
<td></td>
<td>Second course: 12 mg/day on 3 consecutive days (36 mg total dose), administered 12 months after the first treatment course.</td>
<td>Second/Subsequent Courses: 36 billable units (1 dose daily x 3 days) every 12 months thereafter</td>
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<td>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</td>
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**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:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>J0202</td>
<td>Injection, alemtuzumab, 1mg</td>
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**References:**