

PHARMACY POLICY STATEMENT

Ohio Medicaid

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| DRUG NAME | Lemtrada (alemtuzumab) |
| BILLING CODE | J3590 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Outpatient Hospital |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – 60 mg |
| LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY | Click Here |

Lemtrada (alemtuzumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:

1. Member must be between 17 and 65 years of age; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis based on McDonald Diagnostic Criteria; AND
4. Member has documented trial and failure or contraindication to at least **two** formulary multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).
5. **Dosage allowed:** Initial course 12 mg per day for 5 consecutive days (60 mg total dose).

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Doses of Lemtrada separated by at least 12 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Lemtrada (alemtuzumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
- Autoimmune disease
- Chronic lymphoid leukemia
- Malignant tumor of lymphoid hemopoietic and related tissue
- Primary cutaneous T-cell lymphoma, Relapsed or refractory

- Renal transplant rejection, Induction therapy; Prophylaxis
- T-cell prolymphocytic leukemia

| DATE | ACTION/DESCRIPTION |
|------------|--|
| 06/13/2017 | New policy for Lemtrada created. Not covered diagnosis added. Trials of two formulary agents required. |

References:

1. Lemtrada [package insert]. Cambridge, MA; Genzyme, Inc: June, 2016.
2. Lemtrada. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed April 7, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. *Annals of Neurology*. 2011;69(2):292-302. doi:10.1002/ana.22366.

Effective date: 08/09/2017

Revised date: 06/13/2017