Humana. CareSource™

# PHARMACY POLICY STATEMENT
## Kentucky 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)<br>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 17 years of age or older; 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; AND
4. Member has documented trial and failure or contraindication to at least **two** preferred 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. |
| **12/06/2017** | Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer 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: 12/20/2017
Revised date: 12/06/2017