Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

LEMTRADA® (alemtuzumab)

I. Medication Description

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. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use
LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Member is 17 years of age or older.
- Member has one of the following relapsing forms of multiple sclerosis:
  - Relapsing-remitting MS
  - Active secondary-progressive MS.
- Member must not have clinically isolated syndrome (CIS).
- Must be prescribed by, or in consult with, a neurology specialist.
- Member must have experienced at least two relapses during the two years prior and at least one relapse during the year prior to request.
- Prescriber and patient must be enrolled in and meet the conditions of the Lemtrada® REMS program.
- Provider attests to all the following:
  - Member has received baseline skin exam for melanoma.
  - Member does not have any medical conditions that significantly compromise the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation.
  - Member does not have an active infection.
  - Member must have labs completed at baseline (i.e., CBC with differential, serum creatinine levels, urinalysis with urine counts, TSH, etc.) and at periodic intervals for 48 months after the last dose.
  - Provider will monitor for malignancies, including thyroid cancer, melanoma and lymphoproliferative disorder.
- Member has had an inadequate response, history of intolerance, or contraindication to at least two of the following classes:
  - **Interferon:** Interferon β-1a (Avonex® or Rebif®), Interferon β-1b (Betaseron® or Extavia®), Peginterferon beta-1a (Plegridy™)
  - **Glatiramer:** Glatiramer acetate (Copaxone® or Glatopa®)
  - **Fumaric Acid Derivative**: Dimethyl fumarate (Tecfidera®), Monomethyl fumarate (Bafiertam®), Vumerity® (diroximel fumarate)

- **Pyrimidine Synthesis Inhibitor:** Teriflunomide (Aubagio®)
- **Sphingosine 1-Phosphate Receptor Modulator:** Diponimod (Mayzent®), Ozanimod (Zeposia®), fingolimod (Gilenya®)
- **Purine Analog:** Cladribine (Mavenclad®)
- **Anti-CD20 Monoclonal Antibody:** Ofatumumab (Kesimpta®), Ocrelizumab (Ocrevus®)
- **CD20-directed Antibody:** Rituximab (Rituxan®, Riabni™, Truxima®, Ruxience™)
- **Selective Adhesion-Molecule Inhibitor**: Natalizumab (Tysabri®)

- Member is not receiving Lemtrada® in combination with another disease modifying agent for multiple sclerosis.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has experienced a positive clinical response to therapy.
- Member has been adherent to Lemtrada®.
- Provider attests to all of the following:
  - Member is receiving ongoing laboratory monitoring (e.g., CBC with differential, serum creatinine levels, urinalysis with urine counts, TSH).
  - Member does not have any medical condition that significantly compromise the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation.
  - Member does not have an active infection.
  - Provider is monitoring for malignancies, including thyroid cancer, melanoma and lymphoproliferative disorder.
- Annual specialist consult provided if prescriber not a specialist.

V. Quantity Limitations

Max of 12mg IV daily on 5 consecutive days within 12 months initially and 12mg IV daily on 3 consecutive days 12 months after first treatment course

VI. Coverage Duration

Initial approval duration: 1 year (one 5-day course)
Renewal approval duration: 1 year (one 3-day course)