Medical Coverage Policy | Alemtuzumab (Lemtrada)

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 08|18|2015

OVERVIEW

Lemtrada is a multiple sclerosis (MS) disease-modifying agent. Lemtrada can potentially alter the course of disease by lessening the frequency of clinical exacerbations. Lemtrada is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Lemtrada depletes circulating T and B lymphocytes after each treatment course. Lymphocyte counts then increase over time. (1)

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Lemtrada is medically necessary when all of the criteria has been met:

I. Patient has a diagnosis of a relapsing form of multiple sclerosis AND
II. Lemtrada will be used as monotherapy AND
III. Patient is not infected with human immunodeficiency virus (HIV) AND
IV. Patient and prescriber are enrolled in the LEMTRADA REMS program AND
V. Patient has had an inadequate response or intolerance to conventional therapy with THREE of the following (each trial must be a different class):
    a. an interferon beta product (AVONEX®, REBIF®, BETASERON®, EXTAVIA®, or PLEGRIDY™)
    b. glatiramer acetate (COPAXONE®)
    c. natalizumab (TYSABRI®)
    d. fingolimod (GILENYA™)
    e. teriflunomide (AUBAGIO®)
    f. dimethyl fumarate (TECFIDERA®)

Authorization for continued use shall be reviewed once after 12 months when the following criteria are met: The patient received all five daily consecutive doses as part of the initial course of treatment.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for commercial products.

POLICY STATEMENT

Lemtrada may be considered medically necessary for patients 17 years of age or older for the treatment of relapsing forms of multiple sclerosis when the medical criteria has been met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable infusion benefits/coverage.

BACKGROUND

Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and/or delay the accumulation of physical disability who had an inadequate response to two or more drugs indicated for the treatment of MS. Lemtrada is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established. (2)

Regulatory Status
FDA-approved indication: Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who had an inadequate response to two or more drugs indicated for the treatment of MS.

The Lemtrada label includes a boxed warning citing the risk of autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after last dose should be monitored. Lemtrada also carries a boxed warning for infusion reactions which must be administered in an appropriate setting to manage anaphylaxis or serious infusion reactions. (2)

Lemtrada carries another boxed warning for an increased risk of malignancy, including thyroid cancer, melanoma and lymphoproliferative disorders. Baseline and yearly skin exams should be done. (2)

Lemtrada is contraindicated for patients with HIV infection. Lemtrada can cause prolonged reductions of CD4+ lymphocyte counts which can further disease progression in patients with HIV. (2)

The Lemtrada is available only through a restricted distribution program under a REMS program. The Lemtrada REMS Program, a comprehensive risk management program with frequent monitoring, is being implemented to help mitigate the serious risks associated with the medications use.

Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established.

Typical dosing is the first dose is 12mg per day for 5 days. Subsequent dose is no sooner than 12 months and is dosed 12mg per day for 3 days.

CODING

Blue CHip for Medicare and Commercial Products
The following codes are medically necessary when criteria is met

For claims filed prior to 10/1/2015
There is currently no specific HCPCS code for this drug. Claims must be filed with the unlisted HCPCS code and the NDC number.

For claims filed after 10/1/2015
Q9979 - Injection, alemtuzumab, 1 mg - New code effective 10/1/2015

RELATED POLICIES

None

PUBLISHED

Provider Update, October 2015

REFERENCES

1. Genzyme Newspress . Genzyme's Lemtrada Approved by the FDA November 14, 2014. http://news.genzyme.com/press-release/genzymes-lemtrada-approved-fda

2. Lemtrada [package insert]. Cambridge MA: Genzyme Corp.; November 2014.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS