BlueCross BlueShield Federal Employee Program

LEMTRADA
(alemtuzumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lemtrada (alemtuzumab) is 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).

Regulatory Status

FDA-approved indication: 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 had an inadequate response to two or more drugs indicated for the treatment of MS (1).

Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile (1).

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 (1).

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 (1).

Lemtrada is contraindicated for patients with Human Immunodeficiency Virus (HIV) infection. Lemtrada can cause prolonged reductions of CD4+ lymphocyte counts which can further disease progression in patients with HIV (1).

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 (1).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated (2).

Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established (1).

Summary

Lemtrada (alemtuzumab) 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 (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of the MS injectable drugs while maintaining optimal therapeutic outcomes.

References

1. Lemtrada [package insert]. Cambridge MA: Genzyme Corp.; May 2024.
2. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. Neurological Bulletin. 2010;2(1):17-21.