

Lemtrada® (alemtuzumab)



When requesting Lemtrada® (alemtuzumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- Relapsing forms of multiple sclerosis

Approved Off-label Compendial uses²

- None

Coverage Guidelines¹

Multiple sclerosis (MS)

The individual meets **all** of the following criteria

- Has a relapsing form of MS
- Is 17 years of age or older
- Does not have a human immunodeficiency virus (HIV) infection
- Lemtrada will not be used in combination with another MS disease modifying agent

For initial authorization:

- Had an inadequate response to 2 or more drugs indicated for treatment of MS (e.g., interferons, glatiramer acetate)

For reauthorization (2nd treatment course):

- It has been 12 months since first Lemtrada® (alemtuzumab) treatment course
- Has not received 2 or more treatment courses of Lemtrada®(alemtuzumab)

Additional Information for Prescribers¹

- Lemtrada® (alemtuzumab) can cause the following: **(Black Box Warning)***
 - Serious, sometime fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease
 - Serious and life-threatening infusion reactions
 - Increased risk of malignancies including thyroid cancer, melanoma, and lymphoproliferative disorders

*Because of the risk of autoimmune infusion reactions and malignancies, use of Lemtrada® (alemtuzumab) is monitored through a mandatory restricted distribution program, Lemtrada® (alemtuzumab) REMS program. This program requires that

providers, patients, pharmacies and infusion facilities are enrolled and trained regarding the ongoing monitoring requirements for an individual receiving/having received Lemtrada® (alemtuzumab).

- Lemtrada® (alemtuzumab) is contraindicated in an individual who is infected with HIV (**contraindication**)
- Pre-medication with high dose corticosteroids (1,000 mg methylprednisolone or equivalent) is recommended immediately prior to Lemtrada® (alemtuzumab) infusion and for the first 3 days of each treatment course
- The initiation of Lemtrada® (alemtuzumab) should be delayed in an individual with an active infection until the infection is fully controlled
- Live viral vaccines (e.g., FluMist®, oral polio vaccine [OPV], rotavirus, typhoid, yellow fever, measles, varicella, herpes zoster) should not be administered following a course of Lemtrada® (alemtuzumab)
- Complete blood counts with differential, serum creatinine levels and urinalysis with urine counts should be monitored at baseline and at periodic intervals for 48 months after the last dose; thyroid function tests should be done prior to treatment and every 3 months for 48 months after the last dose; skin should be examined at baseline and yearly for individuals receiving Lemtrada® (alemtuzumab)
- Administration of antiviral agent for herpetic prophylaxis is recommended starting on the first day of Lemtrada® (alemtuzumab) dosing and continuing for a minimum of 2 months after completion of Lemtrada® (alemtuzumab) dosing or until CD4+ count is more than 200 cells per microliter, whichever occurs later
- For individuals with a negative or unknown history of varicella or varicella zoster virus (VZV) vaccination, vaccination is recommended if antibody-negative

References

1. Lemtrada® prescribing information. Cambridge, MA: Genzyme Corporation: July 2016. Accessed January 16, 2017. <http://products.sanofi.us/lemtrada/lemtrada.pdf>
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed January 16, 2017. <https://www.micromedexsolutions.com>