

Infusion Protocol

Alemtuzumab (Lemtrada®)

Indication:

Relapsing remitting and active secondary-progressive multiple sclerosis with loss of clinical response to two or more disease modifying treatments (DMT).

Dosing Considerations:

Before initiating (nurse to verify):

- Alemtuzumab is available only through [Lemtrada® REMS \[www.lemtradarems.com\]](http://www.lemtradarems.com) program to prescribers, infusion centers and pharmacies registered through the program.
- Alemtuzumab can only be prescribed in patients who are enrolled in and meet all the requirements of the program and VA Criteria for Use.
- Female patients should use birth control while receiving Alemtuzumab and for 4 months after course of treatment.
- Consider screening patients at high risk for HBV and HCV infection.
- Complete any necessary immunizations at least 6 weeks before initiating treatment.
- Patients should not be immunized with live, viral vaccines during treatment or soon after discontinuation with alemtuzumab.
- Conduct baseline and annual skin exam to monitor for melanoma during or recently after treatment.
- Conduct baseline ECG.
- Determine whether patients have a history of varicella or have been vaccinated for varicella zoster virus (VZV); if not, test the patient for antibodies to VZV and consider vaccination for those who are antibody-negative; postpone initiating treatment until 6 weeks after VZV vaccination.
- Ensure baseline PPD or quantiFERON-TB assay for latent TB.
- Instruct patients to avoid potential sources of *Listeria monocytogenes*.
- Provide the patient with REMS program required handout: [What You Need to Know about Lemtrada® Treatment: A Patient Guide](http://www.lemtradarems.com/Docs/Pdf/Lemtrada%20REMS%20Treatment%20and%20Infusion%20Reactions%20Patient%20Guide_26OCT2020_clean.pdf), [www.lemtradarems.com/Docs/Pdf/Lemtrada%20REMS%20Treatment%20and%20Infusion%20Reactions%20Patient%20Guide_26OCT2020_clean.pdf].

Laboratory testing and monitoring:

- Conduct the following laboratory tests at baseline and at periodic intervals for 48 months following the last treatment course.
 - CBC with differential, serum creatinine and urinalysis with urine cell counts (before treatment and at monthly intervals).

- Test thyroid function (e.g., TSH) before treatment and q3mo thereafter.

At home prior medications: to include antihistamine, analgesic and H2 blocker. Example:

- Cetirizine (Zyrtec®) 10 mg daily for 3 days prior to coming to clinic.
- Acetaminophen (Tylenol®) 650 mg daily for 3 days prior coming to clinic.
- Famotidine (Pepcid®) 20 mg daily for 3 days prior to coming to clinic.

Infusion Therapy:

Dosage: 12 mg Alemtuzumab in 0.9% sodium chloride 100mL IV

Frequency/Duration:

First course: Five consecutive days in year one.

Second course: Three consecutive days in year two.

Infuse over four hours at 25 mL/h.

If infusion related reactions

- 1) Stop infusion immediately;
- 2) Increase primary infusion (saline) to open rate;
- 3) Administer PRN medications for hypersensitivity protocol;
- 4) Notify MD

Pre-Meds:

Methylprednisolone sodium succinate (Solumedrol) in 0.9% sodium chloride 100 mL IV infusion

Dose: 1000 mg

Route: IV

Frequency: Immediately prior to alemtuzumab infusion for the first 3 days of each treatment course.

Rate: Infuse over 60 minutes.

Acetaminophen (Tylenol®) tablet

Dose: 650 mg

Route: Oral

Frequency: Once, 30 minutes prior to alemtuzumab infusion. May be given once as needed during infusion for achiness, headache or fever.

Cetirizine (Zyrtec®) tablet

Dose: 10 mg

Route: Oral

Frequency: Once, at least 30 minutes prior to alemtuzumab infusion.

Famotidine (Pepcid®) tablet

Dose: 20 mg

Route: Oral

Frequency: Once, 30 minutes prior to alemtuzumab infusion.

Diphenhydramine (Benadryl®) injectable

Dose: 50 mg

Route: Intravenous

Frequency: Once, 30 minutes prior to alemtuzumab infusion.

IV Line Care:

0.9% sodium chloride infusion 250 mL

Rate: 30 mL/h

Route: Intravenous

Frequency: Run continuous to keep vein open.

Heparin flush 100 unit/mL

Dose: 500 units

Route: Intravenous

Frequency: PRN for IV-line care.

Infusion Reaction Meds:

Acetaminophen (Tylenol®) tablet

Dose: 650 mg

Route: Oral

Frequency: Once, 30 minutes prior to alemtuzumab infusion. May be given once as needed during infusion for achiness, headache or fever.

Albuterol nebulizer solution

Dose: 2.5 mg

Route: Nebulization

Frequency: PRN for shortness of breath/wheezing.

Diphenhydramine (Benadryl®) injectable

Dose: 25 mg

Route: Intravenous

Frequency: Once PRN, may repeat X1 for urticarial, pruritis, shortness of breath. May repeat in 15 minutes if symptoms not resolved.

Epinephrine (EpiPen®) 0.3 mg/0.3 mL IM auto-injector

Dose: 0.3 mg

Route: Intramuscular

Frequency: Once PRN for anaphylaxis. Notify physician if administered.

Hydrocortisone sodium succinate (Solu-Cortef) injectable

Dose: 100 mg

Route: Intravenous

Frequency: Once PRN for hypersensitivity.

Meperidine (Demerol®)

Dose: 25-50 mg

Route: Intravenous

Frequency: Once for rigors, may repeat.

Outpatient Meds:

Acyclovir (Zovirax®) tablet or equivalent

Dose: 800 mg

Route: Oral

Frequency: Twice daily for herpes prophylaxis for four months or until CD8+ counts rise above 200.

Nursing Orders:

Ensure baseline labs have been drawn within 30 days of initial treatment: CBC w/differential; serum creatinine; TSH; urinalysis with urine cell counts.

- Provide the patient with: [What You Need to Know about Lemtrada® Treatment: A Patient Guide](#) prior to administering alemtuzumab.
- Assess the patient 15 minutes after the infusion begins and as needed.
- Patients should be observed 2 hours after the infusion.
- Monitor vital signs at baseline and 15 minutes after the infusion begins and after the 2-hour observation period at the conclusion of the infusion and as needed throughout the infusion.
- Discontinue the IV line when therapy is complete, and the patient stabilized.
- Complete a Lemtrada® REMS infusion checklist by the last day of each treatment course.

References:

- [CDC: Listeria \(Listeriosis\)](http://www.cdc.gov/listeria/index.html), [www.cdc.gov/listeria/index.html]
- Holmoy T, Vonderlippe H, Leegaard T. Listeria monocytogenes infection associated with alemtuzumab- a case for better preventive strategies. BMC Neurol.2017 Apr 4;17(1):65.
- [IOMSN Alemtuzumab Clinical Information for Nurses: Lemtrada®](https://iomsn.org/wp-content/uploads/2016/07/Lemtrada_PDFPresentation.pdf), [https://iomsn.org/wp-content/uploads/2016/07/Lemtrada_PDFPresentation.pdf]
- [Lemtrada® Dosing and Infusion](http://www.lemtradahcp.com/dosing), [www.lemtradahcp.com/dosing]
- McEwan L, et al. Best Practices in Alemtuzumab Administration. Practical Recommendations for Infusion in Patients with Multiple Sclerosis. J Infus Nurs. 2016 Mar-Apr;39(2):93-104.