



# LEMTRADA REMS PRESCRIBER ENROLLMENT FORM

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at [www.LemtradaREMS.com](http://www.LemtradaREMS.com)

LEMTRADA® (alemntuzumab) is available only through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the REMS are able to prescribe, dispense, administer, and receive LEMTRADA.

## Instructions:

1. Review the LEMTRADA REMS Education Program for Prescribers, including the Prescribing Information
2. Successfully complete the LEMTRADA REMS Knowledge Assessment
3. Complete and submit this LEMTRADA REMS Prescriber Enrollment Form
4. Verify your patients will receive LEMTRADA at a LEMTRADA REMS certified healthcare facility

Please complete all required fields on this form and fax it to 1-855-557-2478. You will receive enrollment confirmation via your preferred method of communication (email or fax) within 2 business days.

\*Indicates a mandatory field.

### LEMTRADA PRESCRIBER INFORMATION (PLEASE PRINT)

Name (Last, First)/Degree\*

Name of Institution or Healthcare Facility\*

Street Address\*

City\*

State\*

ZIP Code\*

Office Phone Number\*

Fax Number\*

Email Address\*

Mobile Phone Number

National Provider Identification (NPI) Number\*

If you are dispensing LEMTRADA from your clinic, a LEMTRADA REMS Healthcare Facility Enrollment Form must also be completed and submitted.

### PRESCRIBER AGREEMENT

By completing this form, I attest that:

- LEMTRADA is 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. LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
- I understand that LEMTRADA is only available through the LEMTRADA REMS and that I must comply with the program requirements in order to prescribe LEMTRADA.
- I have completed the LEMTRADA REMS Education Program for Prescribers, including a review of the LEMTRADA Prescribing Information, and successfully completed the LEMTRADA REMS Knowledge Assessment.
- I understand that by completing the training program and signing this LEMTRADA REMS Prescriber Enrollment Form, I will be enrolled in the LEMTRADA REMS and can prescribe LEMTRADA.
- I understand that I am responsible for reviewing *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with each patient, and counseling each patient on an ongoing basis about the serious risks associated with the use of LEMTRADA and how to mitigate these risks through periodic monitoring.
- I understand that I must enroll all patients being treated with LEMTRADA into the LEMTRADA REMS prior to initiating the patient on treatment with LEMTRADA. I am responsible for completing a LEMTRADA REMS Patient Enrollment Form with the patient (or patient's legal representative), obtaining the patient's (or patient's legal representative's) signature on the form, and submitting the signed form to the LEMTRADA REMS. A completed copy should be provided to the patient and another copy should be stored in the patient's records.
- I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry this card with them at all times in case of an emergency.
- I understand that I must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription.
- I understand that I am responsible for completing baseline lab monitoring within 30 days prior to infusion of LEMTRADA.
- I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient's baseline labs within 30 days prior to the patient's infusion date.

## PRESCRIBER AGREEMENT (CONTINUED)

- I understand the risks of autoimmune conditions and malignancies associated with the use of LEMTRADA, and the need for periodic monitoring in order to identify and mitigate these risks:
  - Complete blood counts with differential obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
  - Serum creatinine levels obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
  - Urinalysis with urine cell counts obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
  - Measure the urine protein to creatinine ratio within 30 days prior to initiation of treatment.
  - Thyroid function tests, such as thyroid stimulating hormone (TSH) level, obtained within 30 days prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion.
  - Serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) and total bilirubin levels prior to initiation of treatment and periodically thereafter.
  - Baseline and yearly skin examinations.
- I understand the risk of stroke during and following the administration of LEMTRADA.
- I will report any adverse events of autoimmune conditions, infusion reactions, stroke or malignancies to Genzyme.
- I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.
- I understand that I will notify Genzyme if a patient is no longer under my care.
- I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

## WEBSITE CONSENT

I understand that the LEMTRADA REMS will publish my name, business address, and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme Corporation and its affiliates from any and all actions, claims, or demands arising out of or in connection with the use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes  No

## SIGNATURE

\_\_\_\_\_  
Prescriber Signature\*

\_\_\_\_\_  
Date\*

\_\_\_\_\_  
Print Name\*

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**If you have any questions regarding the LEMTRADA REMS, call 1-855-676-6326**



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