For Healthcare Facilities to Complete

LEMTRADA alemtuzumab 12mg IV

LEMTRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

Please enroll online at www.LemtradaREMS.com or fax this completed form to the LEMTRADA REMS at 1-855-557-2478

○ New Enrollment
○ Re-enrollment (every 2 years)

*Indicates a mandatory field.

Please complete a separate Healthcare Facility Enrollment Form for each facility site, if applicable.

HEALTHCARE FACILITY INFORMATION (PLEASE PRINT)

Name of Institution or Healthcare Facility*		NPI Number*	
Infusion Facility Address*			
City*		State*	ZIP Code*
Ship-to Street Address (if different)*			
City*		State*	ZIP Code*
Phone Number*	Fax Number*	Email Address	
Name of Authorized Healthcare Facility Representative*		Title*	

Site Affiliation

○ Academic ○ Government ○ Ambulatory/Freestanding ○ Hospital Based ○ Private Practice (in office)

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following REMS requirements:

- I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA.
- I have completed the review of the LEMTRADA REMS Education Program.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRADA by contacting the LEMTRADA REMS or verifying online at www.LemtradaREMS.com prior to initiation of each treatment course.
- I understand the risk of serious infusion reactions during and following the administration of LEMTRADA.
- I understand the risk of stroke during and following the administration of LEMTRADA
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
  - To include the monitoring of patient vital signs before the infusion and periodically during the infusion.
- I understand that my healthcare facility must be equipped with the necessary on-site equipment and personnel to manage anaphylaxis or serious infusion reactions.
- I understand that my healthcare facility must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.

HEALTHCARE FACILITY AGREEMENT (CONTINUED)

- This healthcare facility will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe-use conditions required in the LEMTRADA REMS, including the following:
  - Ensure that a LEMTRADA REMS Patient Enrollment and Prescription Ordering Form is received for each prescription.
  - Ensure that the prescriber is certified and the patient is enrolled and authorized by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website prior to dispensing and administering LEMTRADA.
  - Ensure that the infusion site is equipped to manage infusion reactions.
  - Ensure that LEMTRADA is not dispensed outside of the authorized representative's certified healthcare facility.
  - Prior to the first day of each treatment course, counsel and provide a copy of LEMTRADA Treatment and Infusion Reactions Patient Guide to each patient to inform them about the risk of serious infusion reactions.
  - Observe each patient administered LEMTRADA at my healthcare facility during and for at least 2 hours after each LEMTRADA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRADA infusion.
  - For each patient, complete and return the LEMTRADA REMS Infusion Checklist to the LEMTRADA REMS Program within 5 business days from the patient's last infusion of LEMTRADA within a specific treatment course.
  - Renew enrollment into the LEMTRADA REMS Program every 2 years from the initial enrollment.
- To make available to Genzyme documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.
- To return to Genzyme any unused vials of LEMTRADA for patients who will no longer receive infusions.
- To ensure that a LEMTRADA REMS Patient Authorization and Baseline Lab Form is received for each prescription by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website.
- To ensure that all non-prescribing HCPs who administer LEMTRADA in my healthcare setting are trained using the LEMTRADA REMS Education Program, and a record regarding such training must be maintained.

SIGNATURE

Authorized Healthcare Facility Representative Signature* Date*

Print Name* Title

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

US.MS.LEM.14.11.004-v5-10/2020

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