What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, and malignancies, LEMTRADA® (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS Program.

LEMTTRA DA REMS Program Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS Program to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS Program to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS Program to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS Program in order to receive LEMTRADA.
HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by reviewing the LEMTRADA REMS Education Program for Healthcare Facilities and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS Program, including:
   - All staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained.
   - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
   - The healthcare facility will provide a copy of What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide to the patient on the first day of each treatment course when LEMTRADA is dispensed.
   - The healthcare facility will complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS Program within 5 business days.
   - Enrollment in the LEMTRADA REMS Program must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS Program.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of What You Need to Know About LEMTRADA Treatment: A Patient Guide and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use What You Need to Know About LEMTRADA Treatment: A Patient Guide to counsel your patients on the serious risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS Program.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient’s medical record.

Where to Find REMS Program Information and Resources
To enroll in the LEMTRADA REMS Program, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS Program, call 1-855-676-6326 or visit www.LemtradaREMS.com

Indication
LEMTTRADA is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). 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.

The Prescribing Information includes a boxed WARNING for LEMTRADA.
Please see accompanying Prescribing Information for complete safety information, including boxed WARNING.