

KYMRIAH[®] REMS PROGRAM HOSPITAL ENROLLMENT FORM

Instructions

Kymriah is only available through the Kymriah Risk Evaluation and Mitigation Strategy (REMS) Program. Hospitals and their associated clinics that dispense Kymriah must be certified in the Kymriah REMS Program. In order to become specially certified to dispense Kymriah, hospitals and associated clinics must designate an Authorized Representative to:

- **Complete the certification process by completing the *Kymriah REMS Program Hospital Enrollment Form* on behalf of the hospital and their associated clinics.**
- **Oversee implementation and compliance with the Kymriah REMS Program requirements as outlined below.**

Please complete all required fields below and submit this enrollment form to the REMS Call Center via fax to 1-844-590-0840, E-mail at KymriahREMS@ubc.com or complete it online at www.Kymriah-REMS.com. You will receive a confirmation via E-mail.

If you have any questions, require additional information, or need further copies of any of the Kymriah REMS Program documents, please visit the REMS program website at www.Kymriah-REMS.com, or call the Kymriah REMS Call Center at 1-844-4KYMRIAH (1-844-459-6742).

Authorized Representative Responsibilities

On behalf of my hospital/associated clinics, I understand and agree to comply with the following Kymriah REMS Program requirements:

- I must complete the *Kymriah REMS Live Training Program* and successfully complete the *Kymriah REMS Program Knowledge Assessment*.
 - Those participating in Kymriah clinical trials and/or the pre-approval safety training will be exempt from the live training but will be required to review the REMS materials on the REMS website.
- I must submit this completed *Kymriah REMS Program Hospital Enrollment Form* to the REMS Call Center via fax to 1-844-590-0840, E-mail at KymriahREMS@ubc.com or complete it online at www.Kymriah-REMS.com.
- I must submit the completed *Kymriah REMS Program Knowledge Assessment* form to the REMS Call Center via fax to 1-844-590-0840, E-mail at KymriahREMS@ubc.com or complete it online at www.Kymriah-REMS.com.
- I will oversee implementation and compliance with the Kymriah REMS Program.
- I will ensure that my hospital and associated clinics will establish processes and procedures that are subject to monitoring by Novartis Pharmaceuticals Corporation (NPC), or a third party acting on behalf of NPC to help ensure compliance with the requirements of the Kymriah REMS Program, including the following, before administering Kymriah:
 - a. Ensuring all relevant staff involved in the prescribing, dispensing or administering of Kymriah are trained on the REMS Program requirements and successfully complete the *Kymriah REMS Program Knowledge Assessment*, and maintain records of staff training.
 - b. Performing routine re-education of all staff involved in the prescribing, dispensing or administering of Kymriah and maintaining records of re-training if Kymriah has not been dispensed at least once annually from the date of certification in the Kymriah REMS Program.
 - c. Prior to dispensing Kymriah, put processes and procedures in place to verify a minimum of 2 doses of tocilizumab are available on site for each patient and are ready for immediate administration (within 2 hours).
 - d. Prior to dispensing Kymriah, provide patients and their guardians the *Patient Wallet Card*.

As a condition of certification, the certified hospital must:

- Ensure that if the hospital designates a new authorized representative, the new authorized representative must review the *Kymriah REMS Live Training Program*, complete the *Kymriah REMS Program Knowledge Assessment*, complete a new *Kymriah REMS Program Hospital Enrollment Form* and submit the forms via fax to 1-844-590-0840, E-mail at KymriahREMS@ubc.com or complete it online at www.Kymriah-REMS.com.
- Report any adverse events suggestive of cytokine release syndrome or neurological toxicities of Kymriah to FDA at www.fda.gov/medwatch or by calling 1-800-FDA-1088 or Novartis at <https://psi.novartis.com> or 1-888-669-6682.
- Dispense Kymriah to patients only after verifying that a minimum of 2 doses of tocilizumab are available on-site for each patient and are ready for immediate administration (within 2 hours).
- Maintain documentation of all processes and procedures for the Kymriah REMS Program and provide documentation upon request to Novartis, or a third party acting on behalf of Novartis.
- Comply with audits by Novartis, or a third party acting on behalf of Novartis.

Hospital Information (All Fields Required)

Hospital Name:

Address:

City:

State:

Zip Code:

Phone:

Fax:

Authorized Representative Information (All Fields Required)

First Name:

Last Name:

Credentials: DO MD R.Ph NP/PA Other (please specify)

Phone:

Fax:

E-mail:

Authorized Representative Signature:

Date (MM/DD/YYYY):

Next Steps

1. Please complete all required fields above and submit this enrollment form to the REMS Call Center via fax to 1-844-590-0840, E-mail at KymriahREMS@ubc.com or complete it online at www.Kymriah-REMS.com. You will receive a confirmation via E-mail.
2. Completion of this form does not guarantee your hospital will be certified to administer Kymriah.
3. NPC will assess and provide confirmation of certification via E-mail after processing this enrollment form and a successfully completed Kymriah REMS Program Knowledge Assessment form.
4. Product orders cannot be placed until hospital certification is complete.



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