

RISK EVALUATION AND MITIGATION STRATEGY (REMS) DOCUMENT

YESCARTA (axicabtagene ciloleucel) and TECARTUS (brexucabtagene autoleucel) REMS Program

I. Administrative Information

Application Number: BLA 125643 and BLA 125703

Application Holder: Kite Pharma, Inc.

Initial REMS Approval: 07/2020

Most Recent REMS Update: 07/2020

II. REMS Goals

The goals of the YESCARTA and TECARTUS REMS are to mitigate the risks of cytokine release syndrome (CRS) and neurological toxicities by:

1. Ensuring that hospitals and their associated clinics that dispense YESCARTA and/or TECARTUS are specially certified and have on-site, immediate access to tocilizumab.
2. Ensuring those who prescribe, dispense, or administer YESCARTA and/or TECARTUS are aware of how to manage the risks of CRS and neurological toxicities.

III. REMS Requirements

Kite Pharma, Inc. must ensure that hospitals and their associated clinics, and patients comply with the following requirements:

1. Hospitals and their associated clinics that dispense YESCARTA and/or TECARTUS must:

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|---------------------------------|--|
| To become certified to dispense | <ol style="list-style-type: none">1. Have a minimum of two doses of tocilizumab available on-site for each patient for immediate administration (within 2 hours).2. Designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS Program requirements on behalf of the hospital and their associated clinics.3. Have the authorized representative enroll in the REMS by completing the Hospital Enrollment Form and submitting it to the REMS Program.4. Have the authorized representative complete the Program Training.5. Have the authorized representative successfully complete a Knowledge Assessment and submit it to the REMS Program.6. Train all relevant staff involved in prescribing, dispensing, or administering of YESCARTA and/or TECARTUS on the REMS Program requirements using the Program Training and Adverse Reaction Management Guide.7. Have all relevant staff involved in prescribing, dispensing, or administering YESCARTA and/or TECARTUS successfully complete the Knowledge Assessment.8. Establish processes and procedures to ensure relevant new staff involved in prescribing, dispensing, or administering YESCARTA and/or TECARTUS are trained and complete the Knowledge Assessment.9. Establish processes and procedures to verify that a minimum of two doses of tocilizumab are available on-site for each patient and are ready for immediate administration (within 2 hours).10. Establish processes and procedures to provide patients with the Patient Wallet Card. |
| Before infusion | <ol style="list-style-type: none">11. Verify that a minimum of two doses of tocilizumab are available on-site for each patient and are ready for immediate administration (within 2 hours) through the processes and procedures established as a requirement of the REMS Program. |
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1. Hospitals and their associated clinics that dispense YESCARTA and/or TECARTUS must:

Before discharge 12. Provide the patient with the [Patient Wallet Card](#) through the processes and procedures established as a requirement of the REMS Program.

To maintain certification to dispense, if there is a change in authorized representative 13. Have the new authorized representative enroll in the REMS Program by completing the [Hospital Enrollment Form](#).

To maintain certification to dispense, if YESCARTA or TECARTUS has not been dispensed at least once annually from the date of initial certification in the REMS Program 14. Train all relevant staff involved in prescribing, dispensing, or administering YESCARTA and/or TECARTUS on the REMS Program requirements using the [Program Training](#).
15. Have all relevant staff involved in prescribing, dispensing, or administering YESCARTA and/or TECARTUS successfully complete the [Knowledge Assessment](#).

At all times 16. Report any serious adverse events¹ suggestive of cytokine release syndrome or neurological toxicities to the REMS Program.
17. Maintain records of staff training.
18. Maintain documentation that all processes and procedures are in place and are being followed.
19. Comply with audits by Kite Pharma, Inc. or a third party acting on behalf of Kite Pharma, Inc. to ensure that all training, processes, and procedures are in place and are being followed.

2. Patients who are dispensed YESCARTA or TECARTUS:

Before discharge 1. Receive the [Patient Wallet Card](#).

¹ For the purpose of this REMS, serious adverse event is defined as any adverse experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

Kite Pharma, Inc. must provide training to relevant staff who prescribe, dispense, or administer YESCARTA and/or TECARTUS.

The training includes the following educational material: [Program Training](#). The Training must be provided in-person, live webcast, or on-line.

To support REMS Program operations, Kite Pharma, Inc. must:

1. Ensure that YESCARTA and TECARTUS are distributed only to certified hospitals and their associated clinics.
2. Establish and maintain a [REMS Program website](#) (www.YescartaTecartusREMS.com). The REMS Program website must include the capability to complete training online, maintain records of that training, and the option to print the Prescribing Information, Medication Guides, and REMS materials. The product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website.
3. Make the REMS Program website fully operational and all REMS materials available through the website and call center.
4. Establish and maintain a REMS Program call center for REMS participants at 1-844-454-KITE (5483).
5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS Program.
6. Ensure that hospitals and their associated clinics are able to enroll in the REMS Program in-person, via email, and fax.
7. Notify hospitals and their associated clinics within 7 calendar days after they become certified by the REMS Program.

To ensure REMS participants' compliance with the REMS Program, Kite Pharma, Inc. must:

8. Verify annually that the designated authorized representative remains the same. If different, the hospital and their associated clinics must re-certify with a new authorized representative.
9. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: YESCARTA and/or TECARTUS distribution and dispensing, certification of hospitals and their associated clinics, and audits of REMS participants. These records must be readily available for FDA inspections.
10. Monitor hospitals and their associated clinics on an ongoing basis to ensure the requirements of the REMS Program are being met. Take corrective action if noncompliance is identified, including decertification.
11. Maintain an ongoing annual audit plan of hospitals and their associated clinics.
12. Audit all certified hospitals within 180 calendar days from the first order of YESCARTA and/or TECARTUS for the first patient to ensure that all processes and procedures are in place and functioning to support the requirements of the YESCARTA and TECARTUS REMS Program. Certified hospitals and their associated clinics must also be included in the Kite Pharma, Inc. ongoing annual audit plan.
13. Take reasonable steps to improve implementation of and compliance with the requirements in the YESCARTA and TECARTUS REMS Program based on the monitoring and evaluation of the YESCARTA and TECARTUS REMS program.

IV. REMS Assessment Timetable

Kite Pharma, Inc. must submit REMS Assessments to the FDA at 6 months, 12 months, and annually thereafter from the date of the initial approval of the YESCARTA and TECARTUS REMS (07/24/2020). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Kite Pharma, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the YESCARTA and TECARTUS REMS:

Enrollment Forms

Prescriber:

1. [Hospital Enrollment Form](#)

Training and Educational Materials

Patient:

2. [Patient Wallet Card](#)

Healthcare Setting:

3. [Program Training](#)
4. [Knowledge Assessment](#)
5. [Adverse Reaction Management Guide](#)

Other Materials

6. [REMS Program website](#)

患者信息

YESCARTA®和 TECARTUS™ 可引起可能导致死亡的副作用。

如果您出现以下任何症状，请立即致电或去看您的肿瘤科医生或寻求紧急帮助：

- 发热（100.4°F/38°C 或更高）
- 呼吸困难
- 发冷或寒战
- 意识模糊
- 眩晕或头晕
- 重度恶心、呕吐或腹泻
- 心跳加快或不规则
- 重度疲乏或虚弱

YESCARTA、YESCARTA 徽标、TECARTUS、TECARTUS 徽标、KITE 和 KITE 徽标是 Kite Pharma, Inc. 的商标。GILEAD 是 Gilead Sciences, Inc. 的商标。
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折叠



患者钱包卡

随身携带这张卡片。如果您去急诊室或看任何医生，请出示此卡。

告知任何为您看诊的医务人员您正在接受 YESCARTA®或 TECARTUS™ 治疗。

服用 YESCARTA®或 TECARTUS™ 后，在您接受治疗的地点周围（2 小时车程内）停留至少 4 周。