CARVYKTI™ Risk Evaluation and Mitigation Strategy (REMS)

What is the CARVYKTI REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA).

The FDA has determined that a REMS is necessary to ensure that the benefits of CARVYKTI outweigh the risks of cytokine release syndrome and neurological toxicities. The FDA has required a REMS for CARVYKTI.

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, MLH/MAS AND PROLONGED AND RECURRENT CYTOPENIA

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI. Do not administer CARVYKTI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI. Provide supportive care and/or corticosteroids as needed.

Parkinsonism and Guillain-Barré syndrome and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (MLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI. MLH/MAS can occur with CRS or neurologic toxicities.

Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI.

CARVYKTI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI REMS.

Goals of the REMS

The goal of the CARVYKTI REMS is to mitigate the risk of cytokine release syndrome (CRS) and neurological toxicities by:

- Ensuring that hospitals and their Associated Clinics that dispense CARVYKTI are specially certified and have on-site, immediate access to tocilizumab.
- Ensuring those who prescribe, dispense, or administer CARVYKTI are aware of how to manage the risks of CRS and neurological toxicities.

Hospitals and their Associated Clinics

Hospitals and their Associated Clinics must be certified in the CARVYKTI REMS in order to treat patients with CARVYKTI.

Hospital and Associated Clinics Certification

Indication

CARVYKTI is a T-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with previously refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD19 monoclonal antibody.

Access CARVYKTI REMS Materials and Scroll in the CARVYKTI REMS

Authorized Representatives

Access Training Program and Knowledge Assessment

Hospital and their Associated Clinics Staff

Resources for Healthcare Professionals

- Hospital Enrollment Form
- Training Program
- Adverse Reaction Management Guide
- Knowledge Assessment
- Patient Wallet Card

Download All Resources

Resources for Patients

All patients treated with CARVYKTI receive a Patient Wallet Card. Patients should carry the Wallet Card to remind them of the signs and symptoms of CRS and neurological toxicities that require immediate medical attention. Patients can share this card with any healthcare provider who provides care to them to inform them of receipt of CARVYKTI treatment and when to contact the patient’s oncologist.

- Patient Wallet Card

Reporting Adverse Reactions

Reporting of suspected adverse events after administration of therapy is vital for the continued monitoring of the risk/benefit balance of therapy. To report any serious adverse events* suggestive of CRS or neurologic toxicities contact: Janssen Biotech, Inc at 1-888-746-3238 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Healthcare providers are also encouraged to report any suspected serious adverse events associated with CARVYKTI as detailed above.

*Serious adverse events are defined as any adverse experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse experience, hospitalization or prolongation of existing hospitalization, a persistent or significant disability/impairment, or a congenital anomaly/defect.

Have Questions?

Contact the CARVYKTI REMS by calling 1-844-672-0667

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Hospitals and their Associated Clinics

CARVYKTI REMS Requirements

Hospitals and their Associated Clinics must be certified in the CARVYKTI REMS and have on-site, immediate access to tocilizumab to be able to dispense CARVYKTI.

All relevant Hospitals and their Associated Clinics staff involved in the prescribing, dispensing, or administering of CARVYKTI are trained on the CARVYKTI REMS requirements, and must successfully complete the Knowledge Assessment. The designated Authorized Representative will determine relevant staff who require training.

How does my Hospital and Associated Clinics become certified in the CARVYKTI REMS?

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>Step 1: Designate an Authorized Representative to complete the certification process and oversee implementation and compliance with the CARVYKTI REMS on behalf of the Hospital and Associated Clinics</td>
</tr>
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| 2    | Step 2: Have the Authorized Representative review the following materials:  
  a. Training Program  
  b. Adverse Reaction Management Guide |
| 3    | Step 3: Have the Authorized Representative successfully complete the Knowledge Assessment and submit it to the REMS program |
| 4    | Step 4: Have the Authorized Representative complete the Hospital Enrollment Form and submit it to the REMS program |
| 5    | Step 5: Oversee implementation and compliance with the CARVYKTI REMS:  
  a. Ensure all relevant staff involved in the prescribing, dispensing, or administering of CARVYKTI are trained on the REMS program requirements using the Training Program and the Adverse Reaction Management Guide and successfully complete the Knowledge Assessment  
  b. Have on-site, immediate access to at least two doses of tocilizumab for each patient, for administration within 2 hours after infusion  
  c. Have all relevant staff involved in prescribing, dispensing, or administering CARVYKTI successfully complete the Knowledge Assessment  
  d. Establish processes and procedures to ensure new staff involved in the prescribing, dispensing, or administration of CARVYKTI are trained and complete the Knowledge Assessment  
  e. Establish processes and procedures to provide patients with the Patient Wallet Card  
  f. Prior to dispensing CARVYKTI, put processes and procedures in place to verify on-site, immediate access to at least two doses of tocilizumab for each patient for administration within two hours after infusion  
  g. Before discharge, provide patients or their caregivers with the Patient Wallet Card through the processes and procedures established as a requirement of the REMS program and instruct them to remain close to the location where treatment was received for at least 4 weeks following infusion  
  h. Perform re-education of all staff involved in the prescribing, dispensing, or administering of CARVYKTI on the REMS requirements using the Training Program, the Adverse Reaction Management Guide, and having staff successfully complete the Knowledge Assessment; if CARVYKTI has not been infused at least once annually from the date of certification of the Hospital and Associated Clinics in the CARVYKTI REMS  
  i. Establish processes and procedures that are subject to monitoring by Janssen Biotech, Inc., or a third party acting on behalf of Janssen Biotech, Inc., to ensure compliance with the requirements of the REMS program |

If the Hospital and Associated Clinics designates a new Authorized Representative, the new Authorized Representative must review the Training Program, the Adverse Reaction Management Guide, complete the Knowledge Assessment, and complete a new Hospital Enrollment Form.
Login / Register

Login

OR

Don't have an online account?

Register

To create your web account for the CARVYKTI REMS, please begin by completing the field(s) below and click "Continue".

* I am a(n)
  - Authorized Representative
  - Hospital and Associated Clinics Staff

* Hospital and Associated Clinics REMS ID

Continue

If you have questions about the CARVYKTI REMS or need help enrolling,
call 1-844-672-0067
Monday – Friday, 8:00 AM – 8:00 PM ET

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I am a(n)

- Authorized Representative
- Hospital and Associated Clinics Staff

Please contact your CARVYKTI REMS Authorized Representative if you do not know your Hospital and Associated Clinics REMS ID.

Hospital and Associated Clinics REMS ID

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CARVYKTI™
(ciltacabtagene autoleucel)
Suspension for IV infusion

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  - Hospital and Associated Clinics Staff

* Hospital and Associated Clinics REMS ID

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