CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761291Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
TECVAYLI™ (teclistamab-cqyv) REMS Program

I. Administrative Information

Application Number: BLA 761291

Application Holder: Janssen Biotech, Inc.

Initial REMS Approval: 10/2022

II. REMS Goal

The goal of the TECVAYLI REMS is to mitigate the risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by:

- Educating prescribers on the importance of monitoring patients for signs and symptoms of CRS and neurologic toxicity including ICANS

III. REMS Requirements

Janssen Biotech, Inc. must ensure that prescribers, patients, pharmacies, healthcare settings and wholesaler-distributors comply with the following requirements:

1. Healthcare providers who prescribe TECVALYI must:		
To become certified to prescribe	1.	Review the drug's Prescribing Information.
	2.	Review the Prescriber Training Program and Adverse Reaction Management Guide.
	3.	Successfully complete the Knowledge Assessment and submit it to the REMS.
	4.	Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS.
Before treatment initiation (first dose)	5.	Counsel the patient on: a) how to recognize and respond to signs and symptoms of CRS and neurologic toxicity including ICANS, b) the need to report all symptoms suggestive of CRS and neurologic toxicity including ICANS to their healthcare provider or emergency room provider immediately, and c) to carry the Patient Wallet Card at all times.
	6.	Complete the Patient Wallet Card and provide the Patient Wallet Card to the patient.
At all times	7.	Report serious adverse events suggestive of CRS or neurologic toxicity including ICANS to the REMS.

2. Patients who are prescribed TECVAYLI:		
Before treatment	1.	Receive counseling from the prescriber using the Patient Wallet Card.
At all times	2.	Have the Patient Wallet Card with you and inform other healthcare providers about treatment with TECVAYLI.
3. Pharmacies and healthcare settings that dispense TECVAYLI must:		
To become certified to dispense	1.	Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy and/or healthcare setting.
	2.	Have the authorized representative review the Pharmacy and Healthcare Setting Training Program.
	3.	Have the Authorized Representative enroll in the REMS by completing the Pharmacy and Healthcare Setting Enrollment Form and submitting it to the REMS.
	4.	Train all relevant staff involved in dispensing TECVAYLI on the REMS requirements using the Pharmacy and Healthcare Setting Training Program.
Before dispensing	5.	Obtain authorization to dispense each prescription by contacting the REMS Program to verify the prescriber is certified.
To maintain certification to dispense	6.	If there is a change in the Authorized Representative, have the new Authorized Representative enroll in the REMS by completing the Pharmacy and Healthcare Setting Enrollment Form.
At all times	7.	Report serious adverse events suggestive of CRS and neurologic toxicity including ICANS to the REMS.
	8.	Not distribute, transfer, loan or sell TECVAYLI except to certified pharmacies and healthcare settings.
	9.	Maintain records of staff training.
	10.	Maintain records that processes and procedures are in place and are being followed.
	11.	Maintain records of all TECVAYLI dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.
	12.	Comply with audits carried out by Janssen Biotech, Inc. or a third party acting on behalf of Janssen Biotech, Inc. to ensure that all training, processes, and procedures are in place and are being followed.

4. Wholesaler-distributors that distribute TECVAYLI must:		
To be able to distribute	1.	Establish processes and procedures to ensure that TECVAYLI is distributed only to certified pharmacies & healthcare settings.
	2.	Train all relevant staff involved in distribution on the REMS requirements.
At all times	3.	Distribute only to certified pharmacies and healthcare settings.
	4.	Maintain records that all processes and procedures are in place and are being followed.
	5.	Maintain records of drug distribution and provide these records to the REMS Program at least on a monthly basis.
	6.	Comply with audits carried out by Janssen Biotech, Inc. or a third party acting on behalf of Janssen Biotech, Inc. to ensure that all processes and procedures are in place and are being followed.

Janssen Biotech, Inc. must provide training to healthcare providers who prescribe TECVAYLI. The training includes the following educational materials: Prescriber Training Program, Adverse Reaction Management Guide, and Knowledge Assessment. The training must be provided online.

Janssen Biotech, Inc. must provide training to pharmacies and healthcare settings that dispense TECVAYLI. The training includes the following educational material: Pharmacy and Healthcare Setting Training Program. The training must be provided online.

To inform healthcare providers about the REMS, the risks of CRS and neurologic toxicity including ICANS, and safe use of TECVAYLI, Janssen Biotech, Inc. must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plan
Healthcare providers including oncologists, oncology physician assistants, oncology nurse practitioners, hematologists, and oncology nurses who are likely to prescribe and care for patients treated with TECVAYLI.	**REMS Letters:** Healthcare Provider REMS Letter, Professional Society REMS Letter with attachment REMS Fact Sheet 1. E-mail within 30 calendar days of the date TECVAYLI is first commercially distributed and again 12 months later. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available, or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 2. Disseminate through field-based sales and medical representatives for 12 months from the date TECVAYLI is first commercially distributed.

3. Disseminate within 30 calendar days of the date TECVAYLI is first commercially distributed and again 12 months later through the following professional societies and request the letter or content be provided to their members.
    a. American Society of Clinical Oncology (ASCO); American Society of Hematology (ASH); Advanced Practitioner Society for Hematology and Oncology (APSHO); Oncology Nursing Society (ONS); National Comprehensive Cancer Network (NCCN); Society of Hematologic Oncology (SOHO); Hematology Oncology Pharmacy Association (HOPA); American Pharmacists Association (APhA); American Society of Health-System Pharmacists (ASHP)
4. Disseminate at Professional Meetings where Janssen Biotech, Inc. has a presence for 12 months from the date TECVAYLI is first commercially distributed.

REMS Fact Sheet

1. Disseminate at Professional Meetings where Janssen Biotech, Inc. has a presence for 12 months from the date TECVAYLI is first commercially distributed.
2. Disseminate through field-based sales and medical representatives during the initial and/or follow-up discussion with healthcare providers for 12 months after TECVAYLI is first commercially distributed. Field-based sales and/or medical representatives to orally review the key risk messages contained in the REMS Fact Sheet during the visit with the healthcare provider.

To support REMS operations, Janssen Biotech, Inc. must:

1. Authorize dispensing for each prescription based on verifying the prescriber is certified.
2. Establish and maintain the REMS Website, www.TECVAYLIREMS.com. The REMS Website must include the capability to enroll prescribers, pharmacies and healthcare settings, complete training online, maintain records of that training, and an option to print the Prescribing Information (PI), Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS -specific links to the REMS Website.
3. Make the REMS Website fully operational and all REMS materials available through the website and the REMS Coordinating Center within 60 calendar days post approval of the REMS.
4. Establish and maintain a REMS Coordinating Center for REMS participants at 1- 855-810-8064.
5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the TECVAYLI REMS.
6. Ensure prescribers, pharmacies and healthcare settings can enroll in the REMS online, by fax and e-mail.
7. Ensure pharmacies and healthcare settings are able verify the prescriber is certified by phone and online.

8. Notify prescribers, pharmacies and healthcare settings within 1 calendar day after they become certified in the REMS.

9. Provide certified prescribers access to the database of certified pharmacies and healthcare settings.

10. Provide certified pharmacies and healthcare settings access to the database of certified prescribers.

11. Provide authorized wholesaler-distributors access to a list of certified pharmacies and healthcare settings.

12. Report CRS and neurologic toxicity including ICANS as soon as possible to the FDA but no later than 15 calendar days from the initial receipt of the information by the applicant. This requirement does not affect the applicant's other reporting and follow-up requirements under applicable FDA regulations.

To ensure REMS participants' compliance with the REMS, Janssen Biotech, Inc. must:

13. Verify annually that the designated authorized representative for certified pharmacies and healthcare settings remain the same. If different, the pharmacy/healthcare setting must re-certify with a new authorized representative.

14. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: TECVAYLI distribution and dispensing; certification of pharmacies and healthcare settings; authorized wholesaler-distributors; and audits of REMS participants. These records must be readily available for FDA inspections.

15. Monitor pharmacies, healthcare settings, and wholesaler-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including decertification or deauthorization.

16. Establish a plan for addressing noncompliance with REMS requirements.

17. Audit all certified pharmacies and healthcare settings within 180 calendar days after the pharmacy or healthcare setting receives their first shipment of TECVAYLI and annually to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.

18. Audit wholesaler-distributors that have distributed TECVAYLI within 180 calendar days of being authorized to distribute TECVAYLI, or within 180 calendar days of FDA approval, whichever is later, and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements. Take corrective action if noncompliance is identified.

19. Take reasonable steps to improve operations of and compliance with the requirements in the TECVAYLI REMS based on monitoring and evaluation of the TECVAYLI REMS.

IV. REMS Assessment Timetable

Janssen Biotech, Inc. must submit REMS Assessments to the FDA annually from the date of the initial approval of the REMS (10/25/2022). 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 calendar days before the submission date for that assessment. Janssen Biotech, 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 TECVAYLI REMS:

Communication Materials

1. Healthcare Provider REMS Letter
2. Professional Society REMS Letter
3. REMS Fact Sheet

Enrollment Forms

4. Prescriber Enrollment Form
5. Pharmacy and Healthcare Setting Enrollment Form

Training and Educational Materials

Patient:

6. Patient Wallet Card

Prescriber:

7. Prescriber Training Program
8. Adverse Reaction Management Guide
9. Knowledge Assessment

Pharmacy and Healthcare Setting:

10. Pharmacy and Healthcare Setting Training Program

Other Materials

11. REMS Website

FDA- REQUIRED REMS SAFETY INFORMATION

- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with **TECVAYLI**
- Required REMS Certification to prescribe **TECVAYLI**

Dear Healthcare Provider:

The purpose of this letter is to inform you of important safety information for **TECVAYLI** based on current prescribing information. FDA has required this safety notice as part of the **TECVAYLI** REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity, including ICANS.

Serious Risks of TECVAYLI

- **Cytokine release syndrome (CRS)**, including life-threatening or fatal reactions, can occur in patients receiving **TECVAYLI**.
- Initiate treatment with TECVAYLI step-up dosing schedule to reduce risk of CRS.
- **Neurologic toxicity, including ICANS** and serious and life-threatening reactions, can occur in patients receiving **TECVAYLI**.
- Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** until CRS or neurologic toxicity, including ICANS, resolves or permanently discontinue based on severity.

Enclosed for your review and awareness of these serious risks is the ***TECVAYLI REMS Fact Sheet***, a non-promotional Fact Sheet reviewed by the FDA which will provide you with more information about these risks and the **TECVAYLI** REMS requirements.

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- **TECVAYLI** is ONLY prescribed and/or dispensed by certified prescribers, pharmacies, and healthcare settings.
- Prescribers must counsel patients on signs and symptoms of CRS and neurologic toxicity, including ICANS.
- Complete the ***Patient Wallet Card*** for the patient or caregiver and provide it to them.

Indication

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Adverse Event Reporting

Healthcare providers must report any serious adverse events suggestive of CRS and neurologic toxicity, including ICANS, to Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

For a complete safety profile of **TECVAYLI**, please see the **Prescribing Information** included. For additional details about the REMS, please visit **www.TECVAYLIREMS.com** or contact the **TECVAYLI** REMS Coordinating Center at 1-855-810-8064.

Sincerely,

Janssen Biotech, Inc.

TECVAYLI™ (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

Janssen Oncology

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Reference ID: 5066150

From:
To:
Subject: TECVAYLI REMS REQUIRED SAFETY INFORMATION FOR HEALTHCARE PROVIDERS
Date:
Attachments:

TECVAYLI™
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

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Date

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Serious Risk(s) of TECVAYLI

- **Cytokine release syndrome (CRS),** including life-threatening or fatal reactions, can occur in patients receiving **TECVAYLI**.
- Initiate treatment with **TECVAYLI** step-up dosing schedule to reduce risk of CRS.
- **Neurologic toxicity, including (ICANS)** and serious and life-threatening reactions, can occur in patients receiving **TECVAYLI**.
- Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** until CRS or neurologic toxicity resolves or permanently discontinue based on severity.

Enclosed for your review and awareness of these serious risks is the ***TECVAYLI REMS Fact Sheet***, a non-promotional Fact Sheet reviewed by the FDA which will provide you with more detailed information about these serious risks and the **TECVAYLI** REMS requirements. You can also locate this Fact Sheet online at **www.TECVAYLIREMS.com.**

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** must be aware of how to manage

the risks of CRS and neurologic toxicity, including ICANS.

- **TECVAYLI** is ONLY prescribed and/or dispensed by certified prescribers or pharmacies.
- Prescribers must counsel patients on signs or symptoms of CRS and neurologic toxicity, including ICANS.
- Complete the ***Patient Wallet Card*** for the patient or caregiver and provide it to him/her.

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TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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For a complete safety profile of **TECVAYLI**, please see the Prescribing Information included as an appendix to this letter and can also be located online at **https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf**. For additional details about the REMS, please visit **www.TECVAYLIREMS.com** or contact the TECVAYLI REMS Coordinating Center at 1-855-810-8064.

Sincerely,
Janssen Biotech, Inc

FDA- REQUIRED REMS SAFETY INFORMATION

- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with **TECVAYLI**
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Dear Professional Society,

We request that you share this safety information with your members.

The purpose of this letter is to inform you of important safety information for **TECVAYLI** based on current prescribing information. FDA has required this safety notice as part of the **TECVAYLI** REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity, including ICANS.

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Indication

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For a complete safety profile of **TECVAYLI**, please see the Full **Prescribing Information** included. For additional details about the REMS, please visit **www.TECVAYLIREMS.com** or contact the **TECVAYLI** REMS Coordinating Center at 1-855-810-8064.

Sincerely,

Janssen Biotech, Inc.

TECVAYLI™ (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

Janssen Oncology

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Reference ID: 5066150

From:
To:
Subject: Tecvayli Professional Society Email Letter
Date:
Attachments:

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Serious Risk(s) of TECVAYLI

- **Cytokine release syndrome (CRS),** including life-threatening or fatal reactions, can occur in patients receiving **TECVAYLI**.
- Initiate treatment with **TECVAYLI** step-up dosing schedule to reduce risk of CRS.
- **Neurologic toxicity, including (ICANS)** and serious and life-threatening reactions, can occur in patients receiving **TECVAYLI**.
- Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** until CRS or neurologic toxicity resolves or permanently discontinue based on severity.

Enclosed for your review and awareness of these serious risks is the ***TECVAYLI REMS Fact Sheet***, a non-promotional Fact Sheet reviewed by the FDA which will provide you with more detailed information about these serious risks and the **TECVAYLI** REMS

requirements. You can also locate this Fact Sheet online at **www.TECVAYLIREMS.com.**

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- **TECVAYLI** is ONLY prescribed and/or dispensed by certified prescribers or pharmacies.
- Prescribers must counsel patients on signs or symptoms of CRS and neurologic toxicity, including ICANS.
- Complete the ***Patient Wallet Card*** for the patient or caregiver and provide it to him/her.

Indication

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

For a complete safety profile of **TECVAYLI**, please see the Full **Prescribing Information** included. For additional details about the REMS, please visit **www.TECVAYLIREMS.com** or contact the **TECVAYLI** REMS Coordinating Center at 1-855-810-8064.

Sincerely,
Janssen Biotech, Inc

TECVAYLI™ REMS FACT SHEET

FDA - REQUIRED REMS SAFETY INFORMATION

TECVAYLI REMS Overview

- The **TECVAYLI** Risk Evaluation and Mitigation Strategy (REMS) is a safety program that manages the risks of Cytokine Release Syndrome (CRS) and Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The **TECVAYLI** REMS is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.
- Prescribers, pharmacies and healthcare settings that prescribe and/or dispense **TECVAYLI** must be specially certified and trained on how to manage the risks of CRS and neurologic toxicity, including ICANS.
- Patients or their caregivers must receive the ***Patient Wallet Card*** before treatment initiation (first dose).
- Wholesalers and distributors must ONLY distribute **TECVAYLI** to certified pharmacies and healthcare settings.

What Are the Risks?

- CRS, including fatal or life-threatening reactions, may occur in patients receiving **TECVAYLI**. Initiate treatment with **TECVAYLI** step-up dosing schedule to reduce risk of CRS.
- Serious or life-threatening neurologic toxicity, including ICANS, may occur following treatment with **TECVAYLI**. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** until CRS or neurologic toxicity, including ICANS, resolves or permanently discontinue based on severity.

How Can Healthcare Providers Manage the Risks?

- Follow the **TECVAYLI** step-up dosing schedule as outlined in the ***Prescriber Training Program***.
- Administer pretreatment medications 1 to 3 hours before each dose of **TECVAYLI** to reduce the risk of CRS as outlined in the ***Prescriber Training Program***.
- Complete and provide patients or their caregivers with the ***Patient Wallet Card*** prior to treatment initiation (first dose).
- Instruct patients that they should stay at a healthcare setting for monitoring of signs and symptoms of CRS for 48 hours after administration of all doses within the step-up dosing schedule, including the first treatment dose.
- At the first sign of CRS, immediately evaluate the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue **TECVAYLI** based on severity.
- Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity occur.
- Monitor patients for signs or symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue **TECVAYLI** based on severity per recommendations and consider further management per current practice guidelines.
- For further details on recommended actions taken and treatment guidance for CRS and neurologic toxicity, including ICANS, refer to the ***Prescriber Training Program*** and ***Adverse Reaction Management Guide***.

TECVAYLI™ (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Reference ID: 5066150

TECVAYLI™ REMS FACT SHEET

Key Requirements of the TECVAYLI REMS

Healthcare providers that prescribe TECVAYLI

Receive training on the REMS requirements at www.TECVAYLIREMS.com using the ***Prescriber Training Program*** and the ***Adverse Reaction Management Guide***.

Successfully complete the ***Knowledge Assessment*** online.

Enroll in the REMS by completing the ***Prescriber Enrollment Form*** **online** and submit it to the REMS.

Fax and email options are also available.

If **TECVAYLI** will be dispensed and administered in the same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Counsel patients that they should be hospitalized and monitored for signs and symptoms of CRS and neurologic toxicity, including ICANS, for 48 hours after administration of all doses within the **TECVAYLI** step-up dosing schedule.

Pharmacies and Healthcare Settings that dispense TECVAYLI

Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements.

NOTE: Certified **TECVAYLI** Prescribers cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

Authorized Representative must be trained at www.TECVAYLIREMS.com using the ***Pharmacy and Healthcare Setting Training Program.***

Authorized Representative must enroll the Pharmacy/Healthcare Setting in the REMS by completing the ***Pharmacy and Healthcare Setting Enrollment Form*** online and submit it to the REMS Program. Fax and email options are also available.

Pharmacies and Healthcare Settings must verify prescriber certification in the **TECVAYLI** REMS before dispensing **TECVAYLI**.

Patients

Receive the ***Patient Wallet Card*** before treatment.

Should stay at a healthcare setting for monitoring of signs and symptoms of CRS and neurologic toxicity, including ICANS, for 48 hours after administration of all doses within the **TECVAYLI** step-up dosing schedule.

Wholesaler-Distributors

Establish processes and procedures to ensure that **TECVAYLI** is distributed only to certified pharmacies and healthcare settings.

Train all relevant staff involved in distribution on the **TECVAYLI** REMS requirements.

Maintain records of **TECVAYLI** distribution and provide these records to the REMS Program at least monthly.

Adverse Event Reporting

Healthcare providers must report serious adverse events suggestive of CRS and neurologic toxicity, including ICANS, to Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, to enroll in the **TECVAYLI** REMS, and for all REMS materials go to www.TECVAYLIREMS.com

TECVAYLI™ (teclistamab-cqyv) injection for subcutaneous use 10 mg/mL and 90 mg/mL

For more information and to enroll in the TECVAYLI REMS, go to www.TECVAYLIREMS.com

Reference ID: 5066150

TECVAYLI™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Prescriber Enrollment Form

Instructions

To become a certified prescriber in the TECVAYLI REMS and prescribe TECVAYLI:

- Review the Prescribing Information, the ***Prescriber Training Program*** and ***Adverse Reaction Management Guide***.
- Successfully complete and submit the ***Knowledge Assessment*** and this form online at www.TECVAYLIREMS.com.
- If not enrolling online:
  - Complete all required fields below and submit this form to the REMS Coordinating Center by e-mail at TECVAYLI@JanssenREMS.com, or via fax to 1-877-588-7823.
  - Complete the ***Knowledge Assessment*** and submit it to the REMS Coordinating Center by e-mail at TECVAYLI@JanssenREMS.com, or via fax to 1-877-588-7823.
- The TECVAYLI REMS will verify both the ***Knowledge Assessment*** and ***Prescriber Enrollment Form*** are complete and provide confirmation of certification via e-mail after processing.

If TECVAYLI will be dispensed and administered in this same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Certified TECVAYLI Prescribers cannot be designated as the Authorized Representative for a Pharmacy or Healthcare Setting.

Prescriber Information (Fields marked with an * are REQUIRED)

First Name*:_____ Last Name*:_____

Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify) _____

Specialty* (Select one): ☐ Oncology ☐ Hematology ☐ Internal Medicine/Family Medicine
☐ Other (please specify) _____

National Provider Identifier (NPI)#*: _____ State License #*: _____

Practice/Facility Name*:_____

Address Line 1*:_____

Address Line 2:_____

City*:_____ State*:_____ Zip Code*:_____

e-mail*:_____ Phone*:_____ (xxx) xxx-xxxx Fax:_____ (xxx) xxx-xxxx

TECVAYLI™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Prescriber Enrollment Form

I am a prescriber becoming certified in the TECVAYLI REMS. By signing this form, I agree to comply with all TECVAYLI REMS requirements.

To become certified to prescribe, I must:

- Review the TECVAYLI Prescribing Information.
- Review the ***Prescriber Training Program*** and ***Adverse Reaction Management Guide***.
- Successfully complete the ***Knowledge Assessment*** and submit it to the TECVAYLI REMS.
- Enroll in the TECVAYLI REMS by completing the ***Prescriber Enrollment Form*** and submitting it to the TECVAYLI REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient on:
  - how to recognize and respond to signs and symptoms of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS),
  - the need to report all symptoms suggestive of CRS and neurologic toxicity, including ICANS, to their healthcare provider or emergency room provider immediately,
  - the need to carry the ***Patient Wallet Card*** at all times.
- Complete the ***Patient Wallet Card*** and provide the ***Patient Wallet Card*** to the patient.

At all times, I must:

- Report serious adverse events suggestive of CRS or neurologic toxicity, including ICANS, to the TECVAYLI REMS.

Prescriber Signature*

Date* (MM/DD/YYYY)

Phone: 1-855-810-8064
www.TECVAYLIREMS.com
e-mail: TECVAYLI@JanssenREMS.com
Fax: 1-877-588-7823

TECVAYLI™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the TECVAYLI REMS and dispense TECVAYLI, a pharmacy/healthcare setting must designate an Authorized Representative to:

- Review the ***Pharmacy and Healthcare Setting Training Program***
- Complete this ***Pharmacy and Healthcare Setting Enrollment Form:***
  - Online at www.TECVAYLIREMS.com for immediate enrollment
  - by e-mail at TECVAYLI@JanssenREMS.com, or
  - via fax to 1-877-588-7823.
- The TECVAYLI REMS will verify that the ***Pharmacy and Healthcare Setting Enrollment Form*** is complete and provide confirmation of certification via e-mail after processing.
- TECVAYLI cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

Certified TECVAYLI Prescribers cannot be designated as the Authorized Representative for a Pharmacy or Healthcare Setting.

Pharmacy and Healthcare Setting Information (Fields marked with an * are REQUIRED)

(Please Check One*) ☐ New Certification ☐ Change in Authorized Representative

Pharmacy/Healthcare Setting Name*:_____

Stakeholder Type*: ☐ Pharmacy ☐ Healthcare Setting

Pharmacy/Healthcare Setting National Provider Identifier (NPI)#*: _____ HIN:_____

DEA# (On file with distributor account):_____

Pharmacy/Healthcare Setting Type (select one)*: ☐ Inpatient Hospital Pharmacy ☐ Outpatient Hospital Pharmacy
☐ Oncology Infusion Center ☐ Community Oncology Physician Office ☐ Other (please specify) _____

Address Line 1*:_____

Address Line 2:_____

City*:_____ State*:_____ Zip Code*:_____

Phone*:_____ (xxx) xxx-xxxx Fax*:_____ (xxx) xxx-xxxx

Ship To Information

Ship To Address ☐ **Same as Above** **Ship To Contact Name***:_____

Address Line 1*:_____

Address Line 2:_____

City*:_____ State*:_____ Zip Code*:_____

Phone:_____ (xxx) xxx-xxxx Fax:_____ (xxx) xxx-xxxx

Phone: 1-855-810-8064 www.TECVAYLIREMS.com Fax: 1-877-588-7823
e-mail: TECVAYLI@JanssenREMS.com

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janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

TECVAYLI™ (teclistamab-cqyv) injection for subcutaneous use 10 mg/mL and 90 mg/mL

Reference ID: 5066150

TECVAYLI™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Pharmacy and Healthcare Setting Enrollment Form

Authorized Representative Information (All Fields Required)

First Name*:_____ Last Name*:_____

Credentials* (select one): ☐ PharmD ☐ R.Ph ☐ RN

☐ Other (please specify: e.g., MD, DO, Office Administrator, Practice Manager):_____

Phone*:_____ (xxx) xxx-xxxx Fax*:_____ (xxx) xxx-xxxx e-mail*:_____

Your pharmacy or healthcare setting's information will be shared with Janssen Biotech, Inc.'s wholesaler-distributor partners, to allow your pharmacy or healthcare setting to purchase product.

Authorized Representative Responsibilities

As the Authorized Representative, I must:

- Review the ***Pharmacy and Healthcare Setting Training Program***.
- Complete this ***Pharmacy and Healthcare Setting Enrollment Form*** and submit it to the TECVAYLI REMS.
- Train all relevant staff involved in dispensing TECVAYLI on the TECVAYLI REMS requirements using the ***Pharmacy and Healthcare Setting Training Program***.
- Oversee implementation and compliance with the REMS requirements on behalf of the Pharmacy or Healthcare Setting.

Before dispensing, staff must:

- Obtain authorization to dispense each prescription by contacting the TECVAYLI REMS to verify the prescriber is certified.

At all times, staff must:

- Report serious adverse events suggestive of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) to the TECVAYLI REMS.
- Not distribute, transfer, loan or sell TECVAYLI except to certified pharmacies and healthcare settings.
- Maintain records of all TECVAYLI dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.
- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Comply with audits carried out by Janssen Biotech, Inc. or a third party acting on behalf of Janssen Biotech, Inc. to ensure that all training, processes, and procedures are in place and are being followed.
- If there is a change in Authorized Representative, have the new Authorized Representative enroll in the TECVAYLI REMS by completing the ***Pharmacy and Healthcare Setting Enrollment Form.***

_____ _____

Authorized Representative Signature* Date (MM/DD/YYYY)*

Phone: 1-855-810-8064 www.TECVAYLIREMS.com Fax: 1-877-588-7823
e-mail: TECVAYLI@JanssenREMS.com

TECVAYLI™ REMS PATIENT WALLET CARD

Carry this card with you at all times. **SHOW THIS CARD** to any healthcare professional involved in your care and if you go to the emergency room.

✚ IMPORTANT SAFETY INFORMATION FOR PATIENTS RECEIVING TREATMENT WITH TECVAYLI

TECVAYLI™ (teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Reference ID: 5066150

FOR HEALTHCARE PROFESSIONALS

✚ IMPORTANT SAFETY INFORMATION YOU SHOULD KNOW: TECVAYLI therapy can cause cytokine release syndrome (CRS) or neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) which may be fatal or life threatening. CRS may involve multiple organ systems.

⚠ This Patient has received TECVAYLI.

Name of TECVAYLI Treating Oncologist: _____

Office Phone Number: _____

After Hours Phone Number: _____

Healthcare Setting Name: _____

Dates of TECVAYLI Injections:

- **Step-up Dose 1:** _____
- **Step-up Dose 2:** _____
- **First Treatment Dose :** _____

FOR THE PATIENT

Call your healthcare professional or get emergency help right away if you recognize any of these symptoms:

Symptoms of Cytokine Release Syndrome (CRS):

- Fever (100.4°F or higher)
- Difficulty breathing
- Chills
- Fast heartbeat
- Dizziness or light-headedness
- Feeling anxious
- Confusion or restlessness
- Headache

Symptoms of neurologic problems:

- Headache
- Jerking movements
- Rigid muscles
- Feeling restless
- Numbness and tingling (feeling like "pins and needles")
- Confusion
- Trouble speaking
- Muscle spasms
- Tremor
- Changes in your handwriting
- Problems walking
- Hearing Loss
- Muscle weakness in your body or face
- Double vision
- Burning, throbbing or stabbing pain

You should always ask your doctor about taking other medications while taking TECVAYLI.

IMPORTANT TO REMEMBER: You may be asked to stay in the hospital for 48 hours after administration of all doses within the step-up dosing schedule. If you have any of these symptoms call your doctor or seek emergency medical attention right away! These are not all of the possible symptoms of **TECVAYLI**. Tell your doctor if you have any symptom that bothers you or does not go away.

TECVAYLI™
(teclistamab-cqyv)

PRESCRIBER TRAINING PROGRAM

Risk Evaluation and
Mitigation Strategy (REMS)

TECVAYLI Prescriber Training Module

- This educational module contains information on adverse reactions associated with TECVAYLI, including cytokine release syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The adverse reactions listed within this module are not all inclusive of adverse reactions associated with TECVAYLI.
- Please refer to the full Prescribing Information for additional information.

This training module also provides details related to prescriber requirements of the TECVAYLI REMS.

Training Outline

- Prescriber REMS Requirements (Slides 6-8, 19)
- Risk of Cytokine Release Syndrome (Slides 9-14)
- Risk of Neurologic Toxicity, including ICANS (Slides 15-18)

What is a REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the FDA to manage known or potential serious risks associated with a drug product. The FDA has determined that a REMS is necessary to ensure that the benefits of TECVAYLI outweigh its risks.
- The goal of the TECVAYLI REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by:
    - Educating prescribers on the importance of monitoring patients for signs and symptoms of CRS and neurologic toxicity, including ICANS.

TECVAYLI Indication

- TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Prescriber REMS Requirements

Reference ID: 5066150

Prescriber Certification Requirements

Requirements to become certified to prescribe TECVAYLI are as follows:

- Review this ***Prescriber Training Program***, the ***Adverse Reaction Management Guide***, and the Prescribing Information
- Successfully complete and submit the ***Knowledge Assessment*** to the REMS program
- Complete the ***Prescriber Enrollment Form*** and submit it to the REMS program
- Before treatment initiation (first dose), complete and provide the patient/caregiver with the ***Patient Wallet Card***

At all times

- Report serious adverse events suggestive of CRS or neurologic toxicity, including ICANS, to the REMS program

Certified TECVAYLI Prescribers cannot be designated as the Authorized Representative for a certified Pharmacy or Healthcare Setting*.

*If TECVAYLI will be dispensed and administered in this same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Prescriber Counseling

- Counsel the patient/caregiver on how to recognize and respond to signs and symptoms of CRS and neurologic toxicity, including ICANS, using the ***Patient Wallet Card***, and carry it with them at all times
- Instruct the patient that they should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule, including the first treatment dose
- Instruct the patient of the need to report all symptoms suggestive of CRS and neurologic toxicity, including ICANS, to their healthcare provider or emergency room provider immediately
- Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity, including ICANS resolves

8

Cytokine Release Syndrome (CRS)

Reference ID: 5066150

TECVAYLI Boxed Warning

Cytokine Release Syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI. Initiate treatment with TECVAYLI step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI until neurologic toxicity resolves or permanently discontinue based on severity.

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

Cytokine Release Syndrome

- CRS, including fatal or life-threatening reactions, may occur following treatment with TECVAYLI
- In the clinical trial (n=165), CRS was reported in 72% of patients:
  - step-up dose 1: 42%
  - step-up dose 2: 35%
  - initial treatment dose: 24%
- Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI
- Recurrent CRS occurred in 33% of patients
- Patients developed mostly Grade 1 (50%) and Grade 2 (21%) CRS
- 1 (0.6%) patient developed Grade 3 CRS
- The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose of TECVAYLI
- Median duration of CRS was 2 (range: 1 to 9) days

Clinical Signs and Symptoms of CRS

- Patients should be closely monitored for signs or symptoms of CRS, including fever
- Potentially life-threatening complications of CRS may include:
  - Cardiac dysfunction
  - Adult respiratory distress syndrome
  - Neurologic toxicity
  - Renal and/or hepatic failure
  - Disseminated intravascular coagulation (DIC)

Signs and Symptoms

- Fever
- Chills
- Hypoxia
- Sinus Tachycardia
- Hypotension
- Headache
- Elevated Liver Enzymes

TECVAYLI Step-up Dosing Schedule

Dosing Schedule	Day	TECVAYLI Dose*	
Step-up dosing schedule	Day 1	Step-up dose 1	0.06 mg/kg
	Day 4[b]	Step-up dose 2	0.3 mg/kg
	Day 7[c]	First treatment dose	1.5 mg/kg
Weekly dosing schedule[a]	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg once weekly

[a] See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays.
[b] Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.
[c] First treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.

- Administer the following pretreatment medications 1 to 3 hours before each dose of the TECVAYLI step-up dosing schedule to reduce the risk of CRS:
  - Corticosteroid (oral or intravenous dexamethasone 16 mg)
  - Histamine-1 (H1) receptor antagonist (oral or intravenous diphenhydramine 50 mg or equivalent)
  - Antipyretics (oral or intravenous acetaminophen 650 mg to 1000 mg or equivalent)
- Instruct the patient that they should be hospitalized for 48 hours after administration of all doses within the TECVAYLI step-up dosing schedule

***Dose is based on actual body weight and should be administered subcutaneously**

CRS Management

- At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI based on severity
- The use of myeloid growth factors, particularly granulocyte macrophage-colony stimulating factor (GM-CSF), should be avoided during CRS
- If CRS is suspected:
  - Withhold TECVAYLI until CRS resolves
  - Manage according to the recommendations in Table 3 of the USPI and in the ***Adverse Reaction Management Guide***, and consider further management per current practice guidelines
  - Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS
  - Consider laboratory testing to monitor for disseminated intravascular coagulation (DIC), hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function

Neurologic Toxicity, Including ICANS

Reference ID: 5066150

Neurologic Toxicity, Including ICANS

- Serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), may occur following treatment with TECVAYLI
- In the clinical trial, neurologic toxicity was reported in 57% of patients receiving TECVAYLI
  - The most frequently reported neurologic toxicities were:
    - Headache (25%)
    - Motor dysfunction (16%)
    - Encephalopathy (13%)
    - Sensory neuropathy (15%)
  - Grade 3 or Grade 4 neurologic toxicity occurred in 2.4% of patients treated with TECVAYLI
  - With longer follow-up, Grade 4 seizure and fatal Guillain-Barre Syndrome (1 patient each) occurred in patients who received TECVAYLI

Neurologic Toxicity, Including ICANS

- ICANS was reported in 6% of patients who received TECVAYLI at the recommended dose
  - Recurrent ICANS occurred in 1.8% of patients
  - Patients experienced ICANS following:
    - step-up dose 1 (1.2%)
    - step-up dose 2 (0.6%)
    - initial treatment dose (1.8%)
  - Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI
  - The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days
  - The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia
  - The onset of ICANS can be:
    - concurrent with CRS,
    - following resolution of CRS, or
    - in the absence of CRS

Neurologic Toxicity Management

- Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity occur.
- Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI based on severity per recommendations and consider further management per current practice guidelines.

Recommendations for Management of Neurologic Toxicity (excluding ICANS):

Adverse Reactions	Severity[a]	Actions
Neurologic Toxicity[a] (excluding ICANS)	**Grade 1**	• **Withhold TECVAYLI until neurologic toxicity symptoms resolves or stabilize.[b]**
	Grade 2 Grade 3 (First occurrence)	• **Withhold TECVAYLI until neurologic toxicity symptoms improve to Grade 1 or less** • **Provide supportive therapy.**
	Grade 3 (Recurrent) Grade 4	• **Permanently discontinue TECVAYLI.** • **Provide supportive therapy, which may include intensive care.**

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (CI CTCAE), version 4.03.
[b] See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays.

Adverse Event Reporting

- Reporting of suspected adverse events following administration of therapy is vital for the continued monitoring of the risk/benefit balance of therapy
- Healthcare providers must report any serious adverse event including those suggestive of CRS or neurologic toxicity, including ICANS, to Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Additional TECVAYLI REMS Information

For further information, please visit www.TECVAYLIREMS.com or call 1-855-810-8064

Reference ID: 5066150

TECVAYLI™ Adverse Reaction Management Guide

TECVAYLI™
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

This is supplemental to the TECVAYLI US Prescribing Information (USPI).

Reference ID: 5066150

Management of Cytokine Release Syndrome (CRS)

At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI based on severity *(see Table 3 in USPI*). Manage according to the recommendations in Table 1 below. Identify CRS based on clinical presentation. Clinical signs and symptoms of CRS included, but are not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation). Evaluate for and treat other causes of fever, hypoxia, and hypotension. Consider laboratory testing to monitor for disseminated intravascular coagulation, hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function. Administer supportive care for CRS (including, but not limited to, anti-pyretic agents, intravenous fluid support, vasopressors, supplemental oxygen, etc.) as appropriate.

Table 1: Recommendations for Management of CRS

Grade[a]	Presenting Symptoms	Actions
Grade 1	Temperature ≥100.4°F (38°C)[b]	• Withhold TECVAYLI until CRS resolves. • Administer pretreatment medications prior to next dose of TECVAYLI.[c]
Grade 2	Temperature ≥100.4°F (38°C)[b] with: Hypotension responsive to fluids and not requiring vasopressors. and/or Oxygen requirement of low-flow nasal cannula[d] or blow-by.	• Withhold TECVAYLI until CRS resolves. • Administer pretreatment medications prior to next dose of TECVAYLI.[c] • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI.[c]
Grade 3	Temperature ≥100.4°F (38°C)[b] with: Hypotension requiring one vasopressor with or without vasopressin. and/or Oxygen requirement of high-flow nasal cannula[d], facemask, non-rebreather mask, or Venturi mask.	**First Occurrence of Grade 3 CRS with Duration Less than 48 Hours:** • Withhold TECVAYLI until CRS resolves. • Provide supportive therapy, which may include intensive care. • Administer pretreatment medications prior to next dose of TECVAYLI. • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI.[c] **Recurrent Grade 3 CRS or Grade 3 CRS with Duration 48 hours or Longer:** • Permanently discontinue TECVAYLI. • Provide supportive therapy, which may include intensive care.
Grade 4	Temperature ≥100.4°F (38°C)[b] with: Hypotension requiring multiple vaso-pressors (excluding vasopressin). and/or Oxygen requirement of positive pres-sure (e.g., continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), intubation, and me-chanical ventilation).	• Permanently discontinue TECVAYLI. • Provide supportive therapy, which may include intensive care.

[a] Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for CRS.
[b] Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anticytokine therapy.
[c] See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays.
[d] Low-flow nasal cannula is ≤6 L/min, and high-flow nasal cannula is >6 L/min.

Neurologic Toxicity and ICANS

General management for neurologic toxicity and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) is summarized in Tables 2 and 3 below. At the first sign of neurologic toxicity, including ICANS, withhold TECVAYLI and consider neurology evaluation. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care, for severe or life-threatening neurologic toxicities, including ICANS. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity; withhold or permanently discontinue TECVAYLI based on severity and follow management recommendations as indicated in Tables 2 and 3 below. Manage ICANS according to the recommendations in Table 3 and consider further management per current practice guidelines.

The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. For ICANS or other neurologic toxicity, withhold or permanently discontinue treatment with TECVAYLI based on severity and follow management recommendations. Due to the potential for neurologic toxicity, patients receiving TECVAYLI are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

Table 2: Recommendations for Management of Neurologic Toxicity (excluding ICANS)

Adverse Reaction	Severity[a]	Actions
Neurological Toxicity[a] (excluding ICANS)	Grade 1	• Withhold TECVAYLI until neurologic toxicity symptoms resolves or stabilize.[b]
	Grade 2 Grade 3 (First occurence)	• Withhold TECVAYLI until neurologic toxicity symptoms improve to Grade 1 or less.[b] • Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	• Permanently discontinue TECVAYLI • Provide supportive therapy, which may include intensive care.

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (CI CTCAE), version 4.03.
[b] See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays.

Table 3 - Recommendations for Management of Immune Effector Cell-Associated Neurotoxicity Syndrome

Grade[a]	Presenting Symptoms[b]	Actions
Grade 1	ICE score 7-9[c], or depressed level of consciousness[d]: awakens spontaneously.	• Withhold TECVAYLI until ICANS resolves.[e] • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.
Grade 2	ICE score 3-6[c], or depressed level of consciousness[d]: awakens to voice.	• Withhold TECVAYLI until ICANS resolves. • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI.[e]

Table 3 - Recommendations for Management of Neurologic Toxicity (including ICANS)

Grade[a]	Presenting Symptoms[b]	Actions
Grade 3	ICE score 0-2[c], or depressed level of consciousness[d]: awakens only to tactile stimulus, or seizures[d], either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, • or raised intracranial pressure: focal/local edema on neuroimaging[d].	**First Occurrence of Grade 3 ICANS:** • Withhold TECVAYLI until ICANS resolves. • Administer dexamethasone[f] 10 mg intravenously 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care. • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI.[e] **Recurrent Grade 3 ICANS:** • Permanently discontinue TECVAYLI • Administer dexamethasone[f] 10 mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.
Grade 4	ICE score 0[c], or depressed level of consciousness[d]: either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures[d], either: • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings[d]: • deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure/cerebral edema[d], with signs/symptoms such as: • diffuse cerebral edema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilledema, or • Cushing's triad.	• Permanently discontinue TECVAYLI • Administer dexamethasone[f] 10 mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously and continue methylprednisolone 1,000 mg per day intravenously for 2 or more days. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis • Provide supportive therapy, which may include intensive care.

[a] Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
[b] Management is determined by the most severe event, not attributable to any other cause
[c] If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, e.g., point to clock, pen, button = 3 points); **Following Commands** (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point; and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.
[d] Attributable to no other cause.
[e] See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays.
[f] All references to dexamethasone administration are dexamethasone or equivalent.

TECVAYLI™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Knowledge Assessment

Prescriber Information (All Fields Required)

Prescriber First Name: _____ Prescriber Last Name: _____

NPI #: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Credentials: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify) _____

Phone: _____ Fax: _____ e-mail: _____
(xxx) xxx-xxxx (xxx) xxx-xxxx

_____ _____
Signature Date (MM/DD/YYYY)

As a condition of certification, the prescriber must complete the ***Knowledge Assessment***. All 10 questions must be answered correctly.

The ***Knowledge Assessment*** can be completed online at www.TECVAYLIREMS.com or a completed hard copy can be submitted via fax to 1-877-588-7823 or e-mail at TECVAYLI@JanssenREMS.com. You must also complete the ***Prescriber Enrollment Form*** at www.TECVAYLIREMS.com for your certification to be complete.

The **TECVAYLI** REMS will verify that both the ***Knowledge Assessment*** and ***Prescriber Enrollment Form*** are complete, and will provide confirmation of certification via e-mail after processing.

TECVAYLI™ RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Knowledge Assessment

1 **TECVAYLI is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody:**

A- True
B- False

2 **Patients with CRS may present with the following signs and symptoms, *except*:**

A- Fever
B- Hypotension
C- Tinnitus
D- Hypoxia
E- Tachycardia

3 **Which one of the following is true regarding the time to onset of CRS for TECVAYLI? It typically occurs:**

A- 1-12 days after the most recent dose, with a median duration of 7 days
B- 7-21 days after the most recent dose, with a median duration of 10 days
C- 1-6 days after the most recent dose, with a median duration of 2 days
D- Rarely starts during the first week following TECVAYLI dosing

4 **Which of the following regarding Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) are correct:**

A- ICANS can occur concurrently, after resolution, or in absence of CRS
B- At the first sign of neurologic toxicity including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI based on severity per recommendations and consider further management per current practice guidelines.
C- TECVAYLI should be withheld from patients experiencing ICANS
D- The most common signs or symptoms of ICANS included confusional state and dysgraphia
E- All of the above

5 **As a part of patient/caregiver counseling, which of the following are correct regarding TECVAYLI:**

A- Before treatment initiation (first dose), the ***Patient Wallet Card*** must be provided through the processes and procedures established as a requirement of the REMS program
B- Patients should be hospitalized and monitored for signs and symptoms of CRS and neurologic toxicity for 48 hours after administration of all doses within the TECVAYLI step-up dosing schedule
C- Patients should seek immediate medical attention if they experience signs and symptoms of CRS or neurologic toxicity, including ICANS
D- All of the above

6 **Which neurologic toxicity has been reported at any time during treatment with TECVAYLI:**

A- Headache
B- Confusion
C- Dysphagia
D- Seizure
E- Guillain-Barre Syndrome
F- All of the above

7 **Administer corticosteroids, histamine-1 (H1) receptor antagonists, and antipyretics 1 to 3 hours before each dose of the TECVAYLI step-up dosing schedule to reduce the risk of CRS:**

A- True
B- False

8- **Potentially life-threatening complications of CRS may include:**

A- Cardiac dysfunction
B- Adult respiratory distress
C- Renal and/or hepatic failure
D- Disseminated intravascular coagulation (DIC)
E- All of the above

9- **If CRS is suspected during treatment with TECVAYLI, in addition to withholding TECVAYLI until CRS resolves, which of the following supportive measures should be considered:**

A- Intensive care for severe or life-threatening CRS
B- Intravenous fluid support
C- Laboratory testing for pulmonary, cardiac, renal, and hepatic function, and coagulopathy
D- Supplemental oxygen
E- All of the above

10- **Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for _____ after administration of all doses within the TECVAYLI step-up dosing schedule:**

A- 24 hours
B- 48 hours
C- 5 days
D- 7 days

Phone: 1-855-810-8064 www.TECVAYLIREMS.com Fax: 1-877-588-7823
e-mail: TECVAYLI@JanssenREMS.com

TECVAYLI™
(teclistamab-cqyv)

PHARMACY AND HEALTHCARE SETTING TRAINING PROGRAM

Risk Evaluation and
Mitigation Strategy (REMS)

Reference ID: 5066150

TECVAYLI Pharmacy and Healthcare Setting Training Module

- This training module provides details related to pharmacy and healthcare setting requirements of the TECVAYLI REMS.
- Please refer to the full Prescribing Information for additional information.

What is a REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the FDA to manage known or potential serious risks associated with a drug product. The FDA has determined that a REMS is necessary to ensure that the benefits of TECVAYLI outweigh its risks.
- The goal of the TECVAYLI REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by:
  - Educating prescribers on the importance of monitoring patients for signs and symptoms of CRS and neurologic toxicity, including ICANS.

TECVAYLI Indication

- TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Pharmacy and Healthcare Setting Certification Requirements

Requirements to become certified to dispense TECVAYLI are as follows:

- Designate an Authorized Representative to complete the certification process and oversee implementation and compliance with the TECVAYLI REMS on behalf of the Pharmacy or Healthcare Setting
- Have the Authorized Representative review this ***Pharmacy and Healthcare Setting Training Program***
- Have the Authorized Representative enroll in the REMS by completing the ***Pharmacy and Healthcare Setting Enrollment Form*** and submitting it to the REMS
- Train all relevant staff involved in the dispensing of TECVAYLI on the REMS requirements using this ***Pharmacy and Healthcare Setting Training Program***
- Before dispensing TECVAYLI, obtain authorization to dispense each prescription by contacting the TECVAYLI REMS to verify the prescriber is certified

Pharmacy and Healthcare Setting Requirements

- Any new Authorized Representative must enroll in the REMS program by completing the ***Pharmacy and Healthcare Setting Enrollment Form***

At all times

- Report serious adverse events suggestive of CRS and neurologic toxicity, including ICANS to the REMS
- Maintain records of staff training
- Maintain records that processes and procedures are in place and are being followed
- Comply with audits carried out by Janssen Biotech, Inc. or a third party acting on behalf of Janssen Biotech, Inc. to ensure that all REMS specific processes and procedures are in place and being followed
- Not distribute, transfer, loan or sell TECVAYLI, except to certified pharmacies and healthcare settings

Who Can Be an Authorized Representative?

An Authorized Representative at the Pharmacy can be a:

- Licensed Pharmacist
- Pharmacy Technician
- Any responsible individual assigned by the Pharmacy

An Authorized Representative at the Healthcare Setting can be a:

- Pharmacist
- Registered Nurse
- Any responsible individual assigned by the Healthcare Setting (e.g., Office administrator, Practice manager)

Certified TECVAYLI Prescribers cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

One Authorized Representative must enroll for each Pharmacy or Healthcare Setting and uphold the REMS requirements as stated on the *Pharmacy and Healthcare Setting Enrollment Form*

Reference ID: 5066150

Managing Pharmacy and Healthcare Setting Staff

- The Authorized Representative (AR) may grant Pharmacy and Healthcare Setting Staff access via the *Staff Management* tab in the TECVAYLI REMS Portal
- Once the AR has added the Staff member through this page, the Staff member will receive an automated email
- The staff member will then have the ability to access the Portal to confirm Prescriber Certification prior to dispensing TECVAYLI

How to Confirm Prescriber Certification

- When an order for TECVAYLI is received, the AR or designated staff will log into the TECVAYLI REMS portal at www.TECVAYLIREMS.com
- Select **REMS Dispense Authorization (RDA)**
- After entering either the ordering Prescriber's NPI# or name, and clicking on the Generate Authorization Code, one of the following messages will appear:
  - DO NOT DISPENSE
  - OK TO DISPENSE
    - The RDA code will display for documentation purposes
- TECVAYLI may only be dispensed upon generation of an RDA
- The AR or designated staff may also contact the TECVAYLI REMS Coordinating Center via phone at 1-855-810-8064 to obtain an RDA

Adverse Event Reporting

- Reporting of suspected adverse events following administration of therapy is vital for the continued monitoring of the risk/benefit balance of therapy
- Pharmacy and healthcare setting staff must report any serious adverse event including those suggestive of CRS or neurologic toxicity, including ICANS to Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Additional TECVAYLI REMS Information

For further information, please visit www.TECVAYLIREMS.com or call 1-855-810-8064

Reference ID: 5066150

TECVAYLI™ Risk Evaluation and Mitigation Strategy (REMS)

TECVAYLI REMS

The purpose of the TECVAYLI REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity (ICANS) by educating prescribers on the importance of monitoring patients for signs and symptoms of CRS and neurologic toxicity, including ICANS.

Prescribers

Prescribers must be certified in the TECVAYLI REMS to treat patients with TECVAYLI.

Learn More

Pharmacies and Healthcare Settings

Pharmacies and Healthcare Settings must be certified in the TECVAYLI REMS to dispense TECVAYLI to patients.

Learn More

What is the TECVAYLI REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a safety 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 TECVAYLI outweigh the risks of cytokine release syndrome and neurologic toxicity, including ICANS.

Indication

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Reporting Adverse Reactions

To report any serious adverse events suggestive of CRS or neurologic toxicity contact Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) 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 TECVAYLI as detailed above.

Resources for Prescribers

- *Prescriber Enrollment Form*
- *Prescriber Training Program*
- *Adverse Reaction Management Guide*
- *Knowledge Assessment*
- *Patient Wallet Card*
- *Fact Sheet*
- *Healthcare Provider Letter*
- *Professional Society Letter*

Download All Prescriber Resources

Resources for Pharmacies and Healthcare Settings

- *Pharmacy and Healthcare Setting Enrollment Form*
- *Pharmacy and Healthcare Setting Training Program*

Download All Pharmacy and Healthcare Setting Resources

Resources for Patients

All patients treated with TECVAYLI receive a ***Patient Wallet Card***. Patients should carry the Wallet Card to remind them of the signs and symptoms of CRS and neurologic toxicity, including ICANS, and when to seek immediate medical attention. Patients can share this card with any healthcare provider who provides care to them to inform them of receipt of TECVAYLI treatment and when to contact the patient's oncologist.

- *Patient Wallet Card*

Have Questions?

Contact the TECVAYLI REMS by calling 1-855-810-8064

Prescribers

TECVAYLI REMS Requirements

All Healthcare Providers involved in the prescribing of TECVAYLI are trained on the TECVAYLI REMS requirements and must successfully complete the ***Knowledge Assessment***.

How do I become certified in the TECVAYLI REMS?

1	**Step 1:** Review the following materials: ***Prescriber Training Program*** ***Adverse Reaction Management Guide***
2	**Step 2:** Successfully complete the ***Knowledge Assessment*** and submit it to the REMS program
3	**Step 3:** Complete the ***Prescriber Enrollment Form*** and submit it to the REMS program
4	**Step 4:** Before treatment initiation (first dose), counsel patients and/or their caregivers using the ***Patient Wallet Card***. Complete and provide patients or their caregivers with the ***Patient Wallet Card***. Instruct the patient that they should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule.

Resources for Prescribers

- *Prescriber Enrollment Form*
- *Prescriber Training Program*
- *Adverse Reaction Management Guide*
- *Knowledge Assessment*
- *Patient Wallet Card*
- *Fact Sheet*
- *Healthcare Provider Letter*
- *Professional Society Letter*

Download All Prescriber Resources

Pharmacies and Healthcare Settings

TECVAYLI REMS Requirements

All Pharmacies and Healthcare Settings involved in the dispensing of TECVAYLI must become certified in the TECVAYLI REMS

How does a Pharmacy and Healthcare Setting become certified in the TECVAYLI REMS?

1	**Step 1:** Designate an Authorized Representative for the Pharmacy and Healthcare Setting
2	**Step 2:** Authorized Representative must review the ***Pharmacy and Healthcare Setting Training Program***
3	**Step 3:** Authorized Representative must complete the ***Pharmacy and Healthcare Setting Enrollment Form*** and submit it to the REMS program
4	**Step 4:** Train all relevant staff involved in dispensing TECVAYLI on the REMS requirements using the ***Pharmacy and Healthcare Setting Training Program***

Resources for Pharmacies and Healthcare Settings

Pharmacy and Healthcare Setting Enrollment Form

Pharmacy and Healthcare Setting Training Program

Download All Pharmacy and Healthcare Setting Resources

TECVAYLI™
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

TECVAYLI™ REMS Pharmacy and Healthcare Setting Enrollment

TECVAYLI™ Risk Evaluation and Mitigation Strategy (REMS)

Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the TECVAYLI REMS and dispense TECVAYLI, a pharmacy/healthcare setting must designate an Authorized Representative to:

- Review the ***Pharmacy and Healthcare Setting Training Program***.
- Complete this ***Pharmacy and Healthcare Setting Enrollment Form***:
  - Online at www.TECAYLIREMS.com for immediate enrollment
  - by e-mail at TECVAYLI@JanssenREMS.com, or
  - via fax to 1-877-588-7823.
- The TECVAYLI REMS will verify that the ***Pharmacy and Healthcare Setting Enrollment Form*** is complete and provide confirmation of certification via e-mail after processing.
- TECVAYLI cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

Certified TECVAYLI Prescribers cannot be designated as the Authorized Representative for a Pharmacy or Healthcare Setting.

(Fields marked with an * are REQUIRED)

Pharmacy and Healthcare Information

***Pharmacy/Healthcare Setting National Provider Identifier (NPI)#**

Continue

TECVAYLI™ REMS Pharmacy and Healthcare Setting Enrollment

TECVAYLI™ Risk Evaluation and Mitigation Strategy (REMS)

Pharmacy and Healthcare Setting Enrollment Form

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(Fields marked with an * are REQUIRED)

Pharmacy and Healthcare Information

***Pharmacy/Healthcare Setting National Provider Identifier (NPI)#**

***Enrollment Type (Please Check One)**
○ New Certification ○ Change in Authorized Representative

***Pharmacy/Healthcare Setting Name**
University Hospital

***Stakeholder Type**
○ Pharmacy ○ Healthcare Setting

DEA# (On file with distributor account) **HIN**

***Pharmacy/Healthcare Setting Type (Select one)**
○ Inpatient Hospital Pharmacy ○ Outpatient Hospital Pharmacy
○ Oncology Infusion Center ○ Community Oncology Physician Office
○ Other (please specify)

***Address Line 1** **Address Line 2**

***City** ***State** -- Please Select -- ***Zip Code**

***Phone** ***Fax**

Ship To Information

***Ship To Contact Name**

☐ **Shipping Address - Same as above**

***Address Line 1** **Address Line 2**

***City** ***State** -- Please Select -- ***Zip Code**

Phone **Fax**

Authorized Representative Information

***First Name** ***Last Name**

***Credentials (Select one)**
○ PharmD ○ R.Ph. ○ RN
○ Other (please specify: e.g., MD, DO, Office Administrator, Practice Manager)

***Phone** ***Fax** ***e-mail**

Your pharmacy or healthcare setting's information will be shared with Janssen Biotech, Inc.'s wholesaler-distributor partners, to allow your pharmacy or healthcare setting to purchase product.

Authorized Representative Responsibilities

As the Authorized Representative, I must:

- Review the ***Pharmacy and Healthcare Setting Training Program***.
- Complete the ***Pharmacy and Healthcare Setting Enrollment Form*** and submit it to the TECVAYLI REMS.
- Train all relevant staff involved in dispensing TECVAYLI on the TECVAYLI REMS requirements using the ***Pharmacy and Healthcare Setting Training Program***.
- Oversee implementation and compliance with the REMS requirements on behalf of the Pharmacy or Healthcare Setting.

Before dispensing, staff must:

- Obtain authorization to dispense each prescription by contacting the TECVAYLI REMS to verify the prescriber is certified.

At all times, staff must:

- Report serious adverse events suggestive of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) to the TECVAYLI REMS.
- Not distribute, transfer, loan or sell TECVAYLI except to certified pharmacies and healthcare settings.
- Maintain records of all TECVAYLI dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.
- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Comply with audits carried out by Janssen Biotech, Inc. or a third party acting on behalf of Janssen Biotech, Inc. to ensure that all training, processes, and procedures are in place and are being followed.
- If there is a change in Authorized Representative, have the new Authorized Representative enroll in the TECVAYLI REMS by completing the ***Pharmacy and Healthcare Setting Enrollment Form***.

☐ ***Authorized Representative Signature**

Clear Cancel Submit

Reference ID: 5066150

TECVAYLI™ REMS Pharmacy and Healthcare Setting Enrollment

TECVAYLI™ Risk Evaluation and Mitigation Strategy (REMS)

Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the TECVAYLI REMS and dispense TECVAYLI, a pharmacy/healthcare setting must designate an Authorized Representative to:

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Certified TECVAYLI Prescribers cannot be designated as the Authorized Representative for a Pharmacy or Healthcare Setting.

(Fields marked with an * are REQUIRED)

Pharmacy and Healthcare Information

***Pharmacy/Healthcare Setting National Provider Identifier (NPI)#**

1235567890

***Enrollment Type (Please Check One)**

○ New Certification ○ Change in Authorized Representative

***Pharmacy/Healthcare Setting Name**

University Hospital

***Stakeholder Type**

○ Pharmacy ○ Healthcare Setting

DEA# (On file with distributor account) **HIN**

***Pharmacy/Healthcare Setting Type (Select one)**

○ Inpatient Hospital Pharmacy ○ Outpatient Hospital Pharmacy
○ Oncology Infusion Center ○ Community Oncology Physician Office
◉ **Other (please specify)**

***Other Pharmacy/Healthcare Setting Type**

Other

***Address Line 1** **Address Line 2**

***City** ***State** ***Zip Code**

-- Please Select --

***Phone** ***Fax**

Ship To Information

***Ship To Contact Name**

☑ **Shipping Address - Same as above**

Authorized Representative Information

***First Name** ***Last Name**

***Credentials (Select one)**

○ PharmD ○ R.Ph ○ RN
◉ **Other (please specify: e.g., MD, DO, Office Administrator, Practice Manager)**

***Other Credentials**

Please Specify

***Phone** ***Fax** ***e-mail**

Your pharmacy or healthcare setting's information will be shared with Janssen Biotech, Inc.'s wholesaler-distributor partners, to allow your pharmacy or healthcare setting to purchase product.

Authorized Representative Responsibilities

As the Authorized Representative, I must:

- Review the ***Pharmacy and Healthcare Setting Training Program***.
- Complete the ***Pharmacy and Healthcare Setting Enrollment Form*** and submit it to the TECVAYLI REMS.
- Train all relevant staff involved in dispensing TECVAYLI on the TECVAYLI REMS requirements using the ***Pharmacy and Healthcare Setting Training Program***.
- Oversee implementation and compliance with the REMS requirements on behalf of the Pharmacy or Healthcare Setting.

Before dispensing, staff must:

- Obtain authorization to dispense each prescription by contacting the TECVAYLI REMS to verify the prescriber is certified.

At all times, staff must:

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- Maintain records of all TECVAYLI dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.
- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Comply with audits carried out by Janssen Biotech, Inc. or a third party acting on behalf of Janssen Biotech, Inc. to ensure that all training, processes, and procedures are in place and are being followed.
- If there is a change in Authorized Representative, have the new Authorized Representative enroll in the TECVAYLI REMS by completing the ***Pharmacy and Healthcare Setting Enrollment Form***.

☐ ***Authorized Representative Signature**

Clear Cancel Submit

Reference ID: 5066150

TECVAYLI™
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

TECVAYLI™ REMS Pharmacy and Healthcare Setting Enrollment

Thank you for submitting your information to enroll in the TECVAYLI REMS.

A confirmation of this submission has been sent to the e-mail address provided. You can expect to receive an e-mail with a link to create your online web account.

If you do not receive the e-mail within the next few hours, or would like to update your enrollment information at any time, please contact the TECVAYLI REMS at 1-855-810-8064.

Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARC R THEORET
10/25/2022 10:46:45 AM