

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761342Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document

TECVAYLI® (teclistamab-cqyv) and TALVEY™ (talquetamab-tgvs) REMS

I. Administrative Information

Risk: Cytokine Release Syndrome and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome

Application Number: BLA 761291 and BLA 761342

Application Holder: Janssen Biotech, Inc.

Initial REMS Approval: 10/2022

Most Recent REMS Update: 08/2023

II. REMS Goal

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

- Ensuring prescribers are aware of the importance of monitoring for the signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to TECVAYLI or TALVEY.

III. REMS Requirements

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

1. Healthcare providers who prescribe TECVAYLI and/or TALVEY must:

- | | |
|--|---|
| To become certified to prescribe | <ol style="list-style-type: none">1. Review the drug's Prescribing Information.2. Review the Prescriber Training Program and the Adverse Reaction Management Guide.3. Successfully complete the Knowledge Assessment and submit it to the REMS.4. Enroll in the REMS by completing and submitting the Prescriber Enrollment Form to the REMS. |
| Before treatment initiation (first dose) | <ol style="list-style-type: none">5. Counsel the patient on:<ol style="list-style-type: none">a. how to recognize and respond to signs and symptoms of CRS and neurologic toxicity including ICANSb. the need to report all symptoms suggestive of CRS and neurologic toxicity including ICANS to their healthcare provider or emergency room provider immediately, andc. the need to carry the Patient Wallet Card at all times. |
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	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 and neurologic toxicity, including ICANS, to the REMS.
2. Patients who are prescribed TECVAYLI or TALVEY:		
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 or TALVEY.
3. Pharmacies and healthcare settings that dispense TECVAYLI and/or TALVEY 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 and submitting the Pharmacy and Healthcare Setting Enrollment Form to the REMS.
	4.	Train all relevant staff involved in dispensing TECVAYLI and/or TALVEY 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.	Have a new Authorized Representative enroll in the REMS by completing and submitting the Pharmacy and Healthcare Setting Enrollment Form to the REMS if the Authorized Representative changes.
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 and/or TALVEY 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 and TALVEY dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.

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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.
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4. Wholesalers-distributors that distribute TECVAYLI and/or TALVEY must:

- | | |
|--------------------------|--|
| To be able to distribute | <ol style="list-style-type: none">1. Establish processes and procedures to ensure that TECVAYLI and/or TALVEY are distributed only to certified pharmacies & healthcare settings.2. Train all relevant staff involved in distribution on the REMS requirements. |
| At all times | <ol style="list-style-type: none">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 and submit records of drug distribution to the REMS 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. |
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Janssen Biotech, Inc. must provide training to healthcare providers who prescribe TECVAYLI and/or TALVEY. The training includes the following educational materials: [Prescriber Training Program](#), [Adverse Reaction Management Guide](#), and a [Knowledge Assessment](#). The training must be available online.

Janssen Biotech, Inc. must provide training to pharmacies and healthcare settings that dispense TECVAYLI and/or TALVEY. 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 and the risks and safe use of TECVAYLI and TALVEY, Janssen Biotech, Inc. must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plan
<p>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 and/or TALVEY</p>	<p>REMS Letters: Healthcare Provider REMS Letter, Professional Society REMS Letter with attachment REMS Fact Sheet</p> <ol style="list-style-type: none"> 1. E-mail within 30 calendar days of 08/09/2023 and again 12 months later. <ol style="list-style-type: none"> 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 08/09/2023. 3. Disseminate within 30 calendar days of 08/09/2023 and again 12 months later through the following professional societies and request the letter or content be provided to their members. <ol style="list-style-type: none"> 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 08/09/2023. <p>REMS Fact Sheet</p> <ol style="list-style-type: none"> 1. Disseminate at Professional Meetings where Janssen Biotech, Inc. has a presence for 12 months from 08/09/2023. 2. Disseminate through field-based sales and medical representatives during the initial and/or follow-up discussion with healthcare providers for 12 months after 08/09/2023. 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.TEC-TALREMS.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 at the time TALVEY first becomes commercially available.
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 and TALVEY 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 to obtain authorization to dispense 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 wholesalers-distributors access to a list of certified pharmacies and healthcare settings.
12. Report serious 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 remains 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 and TALVEY distribution and dispensing; certification of pharmacies and healthcare settings; authorized wholesalers-distributors; and audits of REMS participants. These records must be readily available for FDA inspections.
15. Monitor pharmacies, healthcare settings, and wholesalers-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 and maintain 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 or TALVEY and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
18. Audit wholesalers-distributors that have distributed TECVAYLI or TALVEY within 180 calendar days of being authorized to distribute TECVAYLI or TALVEY 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 and TALVEY REMS based on monitoring and evaluation of the TECVAYLI and TALVEY REMS.

IV. REMS Assessment Timetable

Janssen Biotech, Inc. must submit REMS Assessments to the FDA annually from the date of the approval of the TECVAYLI and TALVEY REMS (08/09/2023). 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 and TALVEY REMS:

Enrollment Forms

Prescriber:

1. [Prescriber Enrollment Form](#)

Pharmacy and Healthcare Setting:

2. [Pharmacy and Healthcare Setting Enrollment Form](#)

Training and Educational Materials

Prescriber:

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

Patient:

6. [Patient Wallet Card](#)

Pharmacy and Healthcare Setting:

7. [Pharmacy and Healthcare Setting Training Program](#)

Communication Materials

8. [Healthcare Provider REMS Letter](#)
9. [Professional Society REMS Letter](#)
10. [REMS Fact Sheet](#)

Other Materials

11. [REMS Website](#)

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Communication Plan
2. Elements to Assure Safe Use

- Health care providers who prescribe TECVAYLI and TALVEY are specially certified under 505-1(f)(3)(A)
- Pharmacies and health care settings that dispense TECVAYLI and TALVEY are specially certified under 505-1(f)(3)(B)

3. Implementation System

4. Timetable for Submission of Assessments

TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS) Prescriber Enrollment Form

Instructions

To become certified to prescribe TECVAYLI and TALVEY:

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

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*: _____ Fax: _____
(XXX) XXX-XXXX (XXX) XXX-XXXX

Your practice information (name, location, and contact information) may be listed on a location finder as a location having a TECVAYLI and TALVEY REMS certified prescriber. This location finder may be available to healthcare professionals or patients seeking TECVAYLI or TALVEY REMS certified prescribers.

If you do not want your information listed, please call the TECVAYLI and TALVEY REMS at 1-855-810-8064 or email at **TEC-TAL@JanssenREMS.com**.

Phone: 1-855-810-8064

www.TEC-TALREMS.com
e-mail: **TEC-TAL@JanssenREMS.com**

Fax: 1-877-588-7823



TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS) Prescriber Enrollment Form

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

To become certified to prescribe, I must:

- Review the drug's Prescribing Information.
- Review the **Prescriber Training Program** and the **Adverse Reaction Management Guide**.
- Successfully complete the **Knowledge Assessment** and submit it to the REMS.
- Enroll in the REMS by completing and submitting the **Prescriber Enrollment Form** to the 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, and
 - 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 and neurologic toxicity, including ICANS, to the REMS.

Prescriber Signature*:

Date* (MM/DD/YYYY):

Phone: 1-855-810-8064

www.TEC-TALREMS.com
e-mail: TEC-TAL@JanssenREMS.com

Fax: 1-877-588-7823



TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS) Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified to dispense, pharmacies and healthcare settings must 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.
- Review the **Pharmacy and Healthcare Setting Training Program**.
- Complete this **Pharmacy and Healthcare Setting Enrollment Form**:
 - Online at www.TEC-TALREMS.com for immediate enrollment
 - by e-mail at TEC-TAL@JanssenREMS.com, or
 - via fax to 1-877-588-7823.
- TECVAYLI and TALVEY are currently available to limited pharmacies and healthcare settings. Completion of this form does not guarantee your Pharmacy or Healthcare Setting will be authorized to purchase TECVAYLI or TALVEY.
- The TECVAYLI and TALVEY REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and will provide confirmation of certification via e-mail after processing.
- TECVAYLI and/or TALVEY cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

Prescribers certified in the TECVAYLI and TALVEY REMS 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*: Inpatient Hospital Pharmacy Outpatient Hospital Pharmacy

Oncology Infusion Center Community Oncology Physician Office Specialty Pharmacy

Other (please specify) _____

Address Line 1*: _____ Address Line 2: _____

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

Phone*: _____ Fax*: _____

(XXX) XXX-XXXX

(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: _____ Fax: _____

(XXX) XXX-XXXX

(XXX) XXX-XXXX

Phone: 1-855-810-8064

www.TEC-TALREMS.com

Fax: 1-877-588-7823

e-mail: TEC-TAL@JanssenREMS.com



TECVAYLI® and TALVEY™ 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*: _____ Fax*: _____ e-mail*: _____
(XXX) XXX-XXXX (XXX) XXX-XXXX

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**.
- Enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing TECVAYLI and/or TALVEY on the REMS requirements using the **Pharmacy and Healthcare Setting Training Program**.
- Oversee implementation and compliance with the REMS requirements on behalf of the Pharmacy and/or Healthcare Setting.

Before dispensing, staff must:

- Obtain authorization to dispense each prescription by contacting the 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 REMS.
- Not distribute, transfer, loan or sell TECVAYLI and/or TALVEY except to certified pharmacies and healthcare settings.
- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Maintain records of all TECVAYLI and TALVEY dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.
- 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.
- Have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS if the Authorized Representative changes.

Authorized Representative Signature*:

Date* (MM/DD/YYYY):

Phone: 1-855-810-8064

www.TEC-TALREMS.com
e-mail: TEC-TAL@JanssenREMS.com

Fax: 1-877-588-7823



TECVAYLI[®] and TALVEY[™] Risk Evaluation and Mitigation Strategy (REMS)

PRESCRIBER TRAINING PROGRAM

TECVAYLI and TALVEY REMS Prescriber Training Program

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

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

Training Outline

- **REMS**
- **Indications and Warnings**
- **Dosing**
- **Prescriber REMS Requirements**
- **TECVAYLI and TALVEY**
 - Risk of Cytokine Release Syndrome
 - Risk of Neurologic Toxicity, including ICANS

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 and TALVEY outweigh its risks.
- The goal of the TECVAYLI and TALVEY REMS is to mitigate the risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by:
 - Ensuring prescribers are aware of the importance of monitoring for the signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to TECVAYLI or TALVEY.

Indications

- **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.
- **TALVEY** is a bispecific GPRC5D-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.

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 and TALVEY Risk Evaluation and Mitigation Strategy (REMS).



TALVEY Boxed Warning

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

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur in patients receiving TALVEY. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold or permanently discontinue TALVEY based on severity.

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



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.

TALVEY Step-up Dosing Schedules

Weekly Dosing schedule	Day	Dose ^a	
Step-Up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4 ^b	Step-up dose 2	0.06 mg/kg
	Day 7 ^b	First treatment dose	0.4 mg/kg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter ^c	Subsequent treatment doses	0.4 mg/kg once weekly

^a Based on actual body weight.

^b Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

^c Maintain a minimum of 6 days between weekly doses.

Biweekly Dosing schedule	Day	Dose ^a	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4 ^b	Step-up dose 2	0.06 mg/kg
	Day 7 ^b	Step-up dose 3	0.4 mg/kg
	Day 10 ^c	First treatment dose	0.8 mg/kg
Biweekly (Every 2 Weeks) Dosing Schedule	Two weeks after first treatment dose and every 2 weeks thereafter ^d	Subsequent treatment doses	0.8 mg/kg every 2 weeks

^a Based on actual body weight.

^b Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

^c Dose may be administered between 2 to 7 days after step-up dose 3.

^d Maintain a minimum of 12 days between biweekly (every 2 weeks) doses.

Recommended Pretreatment Medications and Important Dosing Information for TECVAYLI and TALVEY

Administer the following pretreatment medications 1 to 3 hours before each dose in the step-up dosing schedule to reduce the risk of CRS:

- Corticosteroid (oral or intravenous dexamethasone, 16 mg or equivalent)
- Antihistamines (oral or intravenous diphenhydramine, 50 mg or equivalent)
- Antipyretics (oral or intravenous acetaminophen, 650 mg to 1000 mg or equivalent)

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

Instruct the patient that they should be hospitalized for 48 hours after each of the doses within the step-up dosing schedule

Prescriber REMS Requirements

**TECVAYLI REMS has been
replaced by the TECVAYLI
and TALVEY REMS**

www.Tec-TalREMS.com

Phone: 855-810-8064

Prescriber Certification Requirements

Requirements to become **newly certified** to prescribe TECVAYLI and/or TALVEY are as follows:

- Review this **Prescriber Training Program, 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** based on the drug prescribed

At all times

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

Prescribers certified in the TECVAYLI and TALVEY REMS cannot be designated as the Authorized Representative for a certified Pharmacy or Healthcare Setting*.

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

Prescriber Recertification Requirements

If you were previously certified in the TECVAYLI REMS, your certification will be automatically transferred to the TECVAYLI and TALVEY REMS. Please read below to refresh/enhance your product/REMS knowledge.

- Review this **Prescriber Training Program**, the **Adverse Reaction Management Guide**, and the Prescribing Information
- Before treatment initiation (first dose), complete and provide the patient/caregiver with the **Patient Wallet Card** based on the drug prescribed

At all times

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

Prescribers certified in the TECVAYLI and TALVEY REMS cannot be designated as the Authorized Representative for a certified Pharmacy or Healthcare Setting*.

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

Prescriber Counseling

- Instruct the patient that they should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule
- 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 to carry it with them at all times
- 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 step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity, including ICANS resolves

Risk of Cytokine Release Syndrome (CRS)

Cytokine Release Syndrome

Occurrence in Clinical Trial	TECVAYLI (n=165)	TALVEY (n=339)
CRS reported	72%	76%
CRS Grades	50% Grade 1 21% Grade 2 0.6% Grade 3	57% Grade 1 17% Grade 2 1.5% Grade 3 or 4
Step-up dose 1	42%	29%
Step-up dose 2	35%	44%
Initial treatment dose	24%	30% for weekly dosing schedule and 33% for 3rd step-up dose in biweekly schedule
Recurrent CRS	33%	30%
Median time to onset of CRS from last dose	2 days (range: 1 to 6)	27 hours (range: 0.1 to 167)
Median duration of CRS	2 days (range: 1 to 9)	17 hours (range: 0 to 622)

CRS, including fatal or life-threatening reactions, can occur following treatment with TECVAYLI or TALVEY

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

CRS Management

- At the first sign of CRS, immediately evaluate patient for hospitalization and administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI or TALVEY based on severity
- If CRS is suspected:
 - Withhold TECVAYLI or TALVEY until CRS resolves
 - Manage according to the recommendations in the TECVAYLI or TALVEY United States Prescribing Information (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

Risk of Neurologic Toxicity, Including ICANS

Neurologic Toxicity

Serious, life-threatening, or fatal neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), can occur following treatment with TECVAYLI* or TALVEY.

Occurrence in Clinical Trial	TECVAYLI (n=165)	TALVEY (n=339)
Neurotoxicity reported	57%	55%
Grade 3 or 4	2.4%	6%
Frequent neurologic toxicities:		
• ICANS	6%	9%
• Headache	25%	20%
• Motor dysfunction	16%	10%
• Sensory neuropathy	15%	14%
• Encephalopathy	13%	15%

*With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI.

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 or TALVEY based on severity per recommendations and consider further management per current practice guidelines.

Recommendations for Management of Neurologic Toxicity (excluding ICANS^c):

Adverse Reactions	Severity ^a	Actions
Neurologic Toxicity ^a (excluding ICANS)	Grade 1	<ul style="list-style-type: none"> • Withhold TECVAYLI or TALVEY until neurologic toxicity symptoms resolve or stabilize.^b
	Grade 2 Grade 3 (First occurrence)	<ul style="list-style-type: none"> • Withhold TECVAYLI or TALVEY until neurologic toxicity symptoms improve to Grade 1 or less • Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	<ul style="list-style-type: none"> • Permanently discontinue TECVAYLI or TALVEY. • Provide supportive therapy, which may include intensive care.

^a Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.

^b See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays, See Tables 3 and 4 in the USPI for recommendations on restarting TALVEY after dose delays.

^c For Recommendations for Management of ICANS see Table 5 of the TECVAYLI USPI or Table 7 of the TALVEY USPI.

ICANS

Occurrence in Clinical Trial	TECVAYLI (n=165)	TALVEY (n=339)
ICANS reported	6%	9%
Recurrent ICANS	1.8%	3%
Step-up dose 1	1.2%	3%
Step-up dose 2	0.6%	3%
Step-up dose 3 (biweekly dosing)	N/A	1.8%
Initial treatment dose	1.8%	2.6% for the weekly dosing schedule 3.7% for the biweekly schedule
Median time to onset after most recent dose	4 days (range 2 to 8)	2.5 days (range 1 to 16)
Median duration	3 days (range 1 to 20)	2 days (range 1 to 22)
Clinical signs and symptoms may include	<ul style="list-style-type: none"> • Confusional state • Dysgraphia 	<ul style="list-style-type: none"> • Confusional state • Depressed level of consciousness • Disorientation • Somnolence • Lethargy • Bradyphrenia

The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

ICANS Management

- Monitor patients for signs and symptoms of ICANS and treat promptly.
- Counsel patients to seek medical attention should signs or symptoms of ICANS occur.
- At the first sign of ICANS, immediately evaluate the patient and provide supportive care based on severity; withhold or permanently discontinue TECVAYLI or TALVEY based on severity and follow management recommendations.
- Refer to Recommendations for Management of ICANS in the TECVAYLI or TALVEY United States Prescribing Information (USPI).

Adverse Event Reporting

- Reporting of suspected adverse events following administration of therapy is vital for the continued monitoring of the benefit/risk balance of therapy
- For TECVAYLI and TALVEY, 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
- Healthcare providers should report all suspected adverse events or product quality complaints to Janssen at 1-800-Janssen (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch

**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, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect*

Additional TECVAYLI and TALVEY REMS Information

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

TECVAYLI® and TALVEY™ Adverse Reaction Management Guide



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

Management of Cytokine Release Syndrome (CRS)

Cytokine release syndrome, including life-threatening or fatal reactions, occur in patients receiving TECVAYLI or TALVEY. Clinical signs and symptoms of CRS may include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, elevated liver enzymes and sinus tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC). Counsel patients to seek medical attention should signs or symptoms of CRS occur.

At the first sign of CRS, immediately evaluate the patient for hospitalization and administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI or TALVEY based on severity (see **Recommendations for Management of CRS Table in respective product USPI**). Manage according to the recommendations in Table 1 below. Identify CRS based on clinical presentation. 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

CRS Grade ^a	Presenting Symptoms	Actions
Grade 1	Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) ^b	<ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY until CRS resolves.^c Administer pretreatment medications prior to next dose of TECVAYLI^c or TALVEY.^c
Grade 2	Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) ^b with either: <ul style="list-style-type: none"> Hypotension responsive to fluids and not requiring vasopressors, or Oxygen requirement of low-flow nasal cannula or blow-by. 	<ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY until CRS resolves. Administer pretreatment medications prior to next dose of TECVAYLI^c or TALVEY.^c Patients should be hospitalized for 48 hours following the next dose of TECVAYLI^c or TALVEY.^c
Grade 3	Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) ^b with either: <ul style="list-style-type: none"> Hypotension requiring one vasopressor, with or without vasopressin, or Oxygen requirement of high-flow nasal cannula^d, facemask, non-rebreather mask, or Venturi mask 	<p><u>Duration less than 48 hours</u></p> <ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY until CRS resolves. Provide supportive therapy, which may include intensive care. Administer pretreatment medications prior to next dose of TECVAYLI^c or TALVEY.^c Patients should be hospitalized for 48 hours following the next dose of TECVAYLI^c or TALVEY.^c <p><u>Recurrent or duration greater than or equal to 48 hours</u></p> <ul style="list-style-type: none"> Permanently discontinue TECVAYLI or TALVEY. Provide supportive therapy, which may include intensive care.
Grade 4	Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) ^b with either: <ul style="list-style-type: none"> Hypotension requiring multiple vasopressors (excluding vasopressin). Or, oxygen requirement of positive pressure (e.g., continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, and mechanical ventilation) 	<ul style="list-style-type: none"> Permanently discontinue TECVAYLI or TALVEY. Provide supportive therapy, which may include intensive care.

^a Based on American Society for Transplantation and Cellular Therapy (ASTCT) grading for CRS (Lee et al 2019).

^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 (e.g., corticosteroids).

^c See Table 2 in the TECVAYLI USPI or Tables 3 and 4 in the TALVEY USPI for recommendations on restarting TECVAYLI or TALVEY after dose delays for adverse reactions.

^d Low-flow nasal cannula is ≤ 6 L/min, and high-flow nasal cannula is >6 L/min.

Management of Neurologic Toxicity and ICANS

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur in patients receiving TECVAYLI or TALVEY. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia. Counsel patients to seek medical attention should signs or symptoms of ICANS occur. 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 or TALVEY 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 or TALVEY based on severity and follow management recommendations in Tables 2 and 3 below. 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. Due to the potential for neurologic toxicity, patients receiving TECVAYLI or TALVEY 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 or TALVEY 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 ICANS

Grade ^a	Presenting Symptoms ^b	Actions
Grade 1	ICE score 7-9 ^c , or depressed level of consciousness ^d : awakens spontaneously.	<ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY until ICANS resolves.^e Monitor neurologic symptoms, and consider consultation with neurologist and other specialists for further evaluation and management. Consider 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.	<ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY 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. Consider 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 or TALVEY.^e

Grade ^a	Presenting Symptoms ^b	Actions
Grade 3	<p>ICE score 0-2^c, (If ICE score is 0, but the patient is arousable (e.g., awake with global aphasia) and able to perform assessment)</p> <p>or depressed level of consciousness^d: awakens only to tactile stimulus,</p> <p>or seizures^d, either:</p> <ul style="list-style-type: none"> • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, <p>or raised intracranial pressure: focal/local edema on neuroimaging^d.</p>	<p><u>First Occurrence of Grade 3 ICANS:</u></p> <ul style="list-style-type: none"> • Withhold TECVAYLI or TALVEY 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. • Consider 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 or TALVEY.^e <p><u>Recurrent Grade 3 ICANS:</u></p> <ul style="list-style-type: none"> • Permanently discontinue TECVAYLI or TALVEY. • 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. • Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.
Grade 4	<p>ICE score 0^c, (Patient is unarousable and unable to perform ICE assessment)</p> <p>or depressed level of consciousness^d: either:</p> <ul style="list-style-type: none"> • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, <p>or seizures^d, either:</p> <ul style="list-style-type: none"> • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, <p>or motor findings^d:</p> <ul style="list-style-type: none"> • deep focal motor weakness such as hemiparesis or paraparesis, <p>or raised intracranial pressure/cerebral edema^d, with signs/symptoms such as:</p> <ul style="list-style-type: none"> • diffuse cerebral edema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilledema, or • Cushing's triad. 	<ul style="list-style-type: none"> • Permanently discontinue TECVAYLI or TALVEY. • 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. • Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

a Based on 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 and see Table 3 and Table 4 for recommendations on restarting TALVEY after dose delays for adverse reactions.

f All references to dexamethasone administration are dexamethasone or equivalent.

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

Adverse Reaction	Severity ^a	Actions
Neurologic Toxicity ^a (excluding ICANS)	Grade 1	<ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY until neurologic toxicity symptoms resolve or stabilize.^b
	Grade 2 Grade 3 (First occurrence)	<ul style="list-style-type: none"> Withhold TECVAYLI or TALVEY until neurologic toxicity symptoms improve to Grade 1 or less.^b Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	<ul style="list-style-type: none"> Permanently discontinue TECVAYLI or TALVEY. Provide supportive therapy, which may include intensive care.

^a Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.

^b See Table 2 in the USPI for recommendations on restarting TECVAYLI after dose delays and see Table 3 and Table 4 in the USPI for recommendations on restarting TALVEY after dose delays for adverse reactions.

Please visit www.TEC-TALREMS.com for further information and resources.

TECVAYLI® and TALVEY™ 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 11 questions must be answered correctly.

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

The TECVAYLI and TALVEY 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.

1 Which of the following is true for TECVAYLI and TALVEY?

- A- Both are 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.
- B- Both share the same dose and dosing schedule.
- C- Both have a Boxed Warning for the risks of cytokine release syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).
- D- All are true except B.

2 Patients with cytokine release syndrome (CRS) may present with the following signs and symptoms, **except**:

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

3 Which of the following are true regarding the time to onset of CRS for TECVAYLI and TALVEY in the step-up dosing period? It typically occurs:

- A- For TECVAYLI and TALVEY, CRS occurred in 72-76% of patients with most events Grade 1 or 2.
- B- For TECVAYLI, the median time to onset of CRS was 2 days (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days.
- C- For TALVEY, the median time to onset of CRS was 27 hours from the last dose and the median duration was 17 hours.
- D- All of the above

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e-mail: TEC-TAL@JanssenREMS.com

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TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS) Knowledge Assessment

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 ICANS, immediately evaluate the patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI or TALVEY based on severity per recommendations and consider further management per current practice guidelines.
- C- TECVAYLI or TALVEY should be withheld from patients experiencing ICANS.
- D- In clinical trials, ICANS were reported in 6% of patients who received TECVAYLI and in 9% of patients who received TALVEY.
- E- All of the above

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

- 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.
- B- Patients 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 step-up dosing schedule for TECVAYLI and each of the first 3 doses within the TALVEY step-up dosing schedule.
- C- Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of the step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.
- D- Patients should seek immediate medical attention if they experience signs and symptoms of CRS or neurologic toxicity, including ICANS.
- E- All of the above

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

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

7 Which can be signs and symptoms associated with ICANS:

- A- Confusional state
- B- Depressed level of consciousness
- C- Disorientation
- D- Somnolence
- E- Lethargy
- F- Bradyphrenia
- G- All of the above

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

- A- True
- B- False

9 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

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

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

11 For TECVAYLI and TALVEY, due to the risks of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for _____ after administration of all doses within the step-up dosing schedule for TECVAYLI and each of the first 3 doses within the TALVEY step-up dosing schedule:

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

Phone: 1-855-810-8064

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e-mail: TEC-TAL@JanssenREMS.com

Fax: 1-877-588-7823

*Applies only if patient is receiving TALVEY at a treatment dose of 0.8 mg/kg

• Step-up Dose 3*: _____

• First Treatment Dose: _____

• Step-up Dose 1: _____

• Step-up Dose 2: _____

Dates of Injections: _____

Dosing Schedule: Weekly Dosing Bi-Weekly Dosing (Please check one.)

Healthcare Setting Name: _____

After Hours Phone Number: _____

Office Phone Number: _____

Name of Treating Oncologist: _____

⚠ This Patient has received: TECVAYLI TALVEY (Please check one.)

Complete the Patient Wallet Card based on the drug prescribed and provide the Patient Wallet Card to the patient.

+ IMPORTANT SAFETY INFORMATION YOU SHOULD KNOW: TECVAYLI and TALVEY 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.

FOR HEALTHCARE PROFESSIONALS

TECVAYLI® and TALVEY™ 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 or TALVEY



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
- Feeling confused or disoriented
- Being less alert or aware
- Feeling sleepy
- Low energy (lethargy)
- Slowness or difficulty thinking
- Seizures
- Memory Loss
- Jerking movements
- Rigid muscles
- Feeling restless
- Numbness and tingling (feeling like “pins and needles”)
- Trouble speaking or writing
- Muscle spasms
- Shaking (tremors)
- 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 TECVALYI or TALVEY.



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** or **TALVEY**. Tell your doctor if you have any symptom that bothers you or does not go away.

TECVAYLI[®] and TALVEY[™] Risk Evaluation and Mitigation Strategy (REMS)

PHARMACY AND HEALTHCARE SETTING TRAINING PROGRAM

All relevant staff involved in dispensing TECVAYLI and/or TALVEY on the REMS requirements must be trained on this Pharmacy and Healthcare Setting Training Program.

TECVAYLI and TALVEY REMS

www.Tec-TalREMS.com

Phone: 855-810-8064

***TECVAYLI REMS has been replaced by the TECVAYLI and TALVEY REMS**

TECVAYLI and TALVEY REMS Pharmacy and Healthcare Setting Training Program

- This training provides details related to pharmacy and healthcare setting requirements of the TECVAYLI and TALVEY REMS.
- Please refer to each product's 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 and TALVEY outweigh its risks.
- The goal of the TECVAYLI and TALVEY REMS is to mitigate the risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by:
 - Ensuring prescribers are aware of the importance of monitoring for the signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to TECVAYLI or TALVEY.

Indications

- **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.
- **TALVEY** is a bispecific GPRC5D-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 and/or TALVEY are as follows:

- Designate an Authorized Representative (AR) to complete the certification process and oversee implementation and compliance with the REMS requirements 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 and/or TALVEY on the REMS requirements using this **Pharmacy and Healthcare Setting Training Program**
- Before dispensing TECVAYLI or TALVEY, obtain a **REMS Dispense Authorization (RDA)** code prior to dispensing each prescription by contacting the TEC-TAL REMS to verify the prescriber is certified

Pharmacy and Healthcare Setting Reattestation Requirements

Requirements for Pharmacies and Healthcare Settings that are currently certified to dispense TECVAYLI are as follows:

- Have the currently designated Authorized Representative review this ***Pharmacy and Healthcare Setting Training Program***
- Have the Authorized Representative complete the reattestation on TEC-TALREMS.com
 - The Authorized Representative may obtain an RDA for TECVAYLI prior to completing reattestation by contacting the REMS Coordinating Center.
 - Staff will be able to continue to obtain RDAs through the portal for TECVAYLI.
 - RDAs for TALVEY will only be available upon completion of Authorized Representative reattestation.
- Train all relevant staff involved in the dispensing of TECVAYLI and/or TALVEY on the REMS requirements using this ***Pharmacy and Healthcare Setting Training Program***
- Before dispensing TECVAYLI or TALVEY, obtain a **REMS Dispense Authorization (RDA)** code prior to dispensing each prescription by contacting the TEC-TAL 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, neurologic toxicity or ICANS to the REMS
- Maintain records of staff training
- Maintain records that processes and procedures are in place and are being followed
- Maintain records of all TECVAYLI and TALVEY dispenses and provide data to the REMS and Wholesaler-Distributor, as requested
- 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 or TALVEY, 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)

Prescribers who are certified in the TECVAYLI and TALVEY REMS cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

Each Pharmacy or Healthcare Setting must designate an Authorized Representative to enroll in the REMS and uphold the REMS requirements as stated on the Pharmacy and Healthcare Setting Enrollment Form.

The Authorized Representative can be responsible for multiple Pharmacy and Healthcare Setting locations.

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 and TALVEY REMS Portal
- Once the Authorized Representative 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 or TALVEY

How to Confirm Prescriber Certification

- When an order for TECVAYLI or TALVEY is received, the Authorized Representative or designated staff will log into the TECVAYLI and TALVEY REMS portal at **www.TEC-TALREMS.com**
- Select **REMS Dispense Authorization (RDA)**
- After selecting TECVAYLI or TALVEY, 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 and/or TALVEY may only be dispensed upon generation of an RDA**
- The Authorized Representative or designated staff may also contact the TECVAYLI and TALVEY REMS Coordinating Center via phone at 1-855-810-8064 to obtain an RDA
- Record the Date, RDA code, drug name, dose, and prescriber in a log or medical records for audit purposes

Adverse Event Reporting

- Reporting of suspected adverse events following administration of therapy is vital for the continued monitoring of the benefit/risk balance of therapy
- For TECVAYLI and TALVEY, Pharmacy and Healthcare setting staff 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
- Pharmacy and Healthcare setting staff should report all suspected adverse events or product quality complaints to Janssen at 1-800-Janssen (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch

**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, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect*

Additional TECVAYLI and TALVEY REMS Information

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

Please note that **TECVAYLIREMS.com** and **TALVEYREMS.com** will redirect to
www.TEC-TALREMS.com.

FDA-REQUIRED REMS SAFETY INFORMATION

The **TECVAYLI**[®] **REMS** is now called the **TECVAYLI**[®] and **TALVEY**[™] **REMS**.

- For Prescribers certified in the **TECVAYLI REMS**, certification will automatically be transferred to the **TECVAYLI and TALVEY REMS**. Prescribers must review each product's USPI, **Adverse Reaction Management Guide** and the **Prescriber Training Program**.
- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with **TECVAYLI** and **TALVEY**

Dear Healthcare Provider:

The **TECVAYLI REMS** has been replaced by the **TECVAYLI and TALVEY REMS**.

- As a prescriber previously certified in the **TECVAYLI REMS**, your certification will be automatically transferred to the **TECVAYLI and TALVEY REMS** and you will be able to prescribe both **TECVAYLI** and **TALVEY**.
- Prescribers must review each product's USPI, the **Adverse Reaction Management Guide**, and the **Prescriber Training Program**.

Serious Risks of **TECVAYLI** and **TALVEY**

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

Enclosed for your review and awareness of these serious risks is the **TECVAYLI and TALVEY 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 and TALVEY REMS** requirements.

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** and/or **TALVEY** must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- **TECVAYLI** and **TALVEY** are 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, using the **Patient Wallet Card**.
- Complete the **Patient Wallet Card** for the patient or caregiver and provide it to him/her.

Indications

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed and CD3-directed 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.

TALVEY is a bispecific GPRC5D-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.

Healthcare providers should report all suspected adverse events or product quality complaints to Janssen at 1-800-Janssen (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

For complete safety profiles of **TECVAYLI** and **TALVEY**, please see the Prescribing Information included. For additional details about the REMS, please visit www.TEC-TALREMS.com or contact the **TECVAYLI and TALVEY REMS** Coordinating Center at 1-855-810-8064. Please note that **TECVAYLIREMS.com** and **TALVEYREMS.com** will redirect to www.TEC-TALREMS.com.

Sincerely,

Janssen Biotech, Inc.

FDA-REQUIRED REMS SAFETY INFORMATION

The **TECVAYLI® REMS** is now called the **TECVAYLI® and TALVEY™ REMS**.

- For Prescribers certified in the **TECVAYLI REMS**, certification will automatically be transferred to the **TECVAYLI and TALVEY REMS**. Prescribers must review each product's USPI, **Adverse Reaction Management Guide** and the **Prescriber Training Program**.
- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with **TECVAYLI** and **TALVEY**

Dear Professional Society:

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

The **TECVAYLI REMS** has been replaced by the **TECVAYLI and TALVEY REMS**.

- Prescribers previously certified in the **TECVAYLI REMS**, will be automatically transferred to and certified in the **TECVAYLI and TALVEY REMS**.
- New prescribers must become certified in the **TECVAYLI and TALVEY REMS** to prescribe each drug.

Serious Risks of **TECVAYLI** and **TALVEY**

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

Enclosed for your review and awareness of these serious risks is the **TECVAYLI and TALVEY 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 and TALVEY REMS** requirements.

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** and/or **TALVEY** must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- **TECVAYLI** and **TALVEY** are 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, using the **Patient Wallet Card**.
- Complete the **Patient Wallet Card** for the patient or caregiver and provide it to him/her.

Indications

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed and CD3-directed 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.

TALVEY is a bispecific GPRC5D-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 additional details about the REMS, please visit www.TEC-TALREMS.com or contact the **TECVAYLI and TALVEY REMS** Coordinating Center at 1-855-810-8064. Please note that **TECVAYLIREMS.com** and **TALVEYREMS.com** will redirect to **www.TEC-TALREMS.com**.

Sincerely,

Janssen Biotech, Inc.

TECVAYLI® and TALVEY™ REMS FACT SHEET

FDA-REQUIRED REMS SAFETY INFORMATION

TECVAYLI and TALVEY REMS Overview

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

Update

- The **TECVAYLI and TALVEY REMS** replaces the **TECVAYLI REMS**.
- For prescribers, pharmacies, and healthcare settings enrolled and certified in the **TECVAYLI REMS**, the enrollment and certification will be automatically transferred to the **TECVAYLI and TALVEY REMS**.
- Prescribers must review each product's USPI, the **Adverse Reaction Management Guide**, and the **Prescriber Training Program**.
- The Authorized Representative for the pharmacy or healthcare setting is required to complete a re-attestation in the **TECVAYLI and TALVEY REMS** before purchasing and dispensing **TALVEY**. Pharmacies and Healthcare Settings may continue purchasing and dispensing **TECVAYLI** prior to completing their re-attestation.

What Are the Risks?

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

How Can Healthcare Providers Manage the Risks?

- Follow the **TECVAYLI** or **TALVEY** step-up dosing schedule as outlined in the **Prescriber Training Program**.
- Administer pretreatment medications 1 to 3 hours before each dose of **TECVAYLI** or **TALVEY** step-up dosing schedule to reduce the risk of CRS as outlined in the **Prescriber Training Program**.
- Complete the **Patient Wallet Card** based on the drug prescribed and provide patients or their caregivers with the **Patient Wallet Card** prior to treatment initiation (first 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** or **TALVEY** based on severity.
- Instruct patients that they should be hospitalized for monitoring of signs and symptoms of CRS for 48 hours after administration of all doses within the step-up dosing schedule.
- Counsel patients to seek medical attention should signs or symptoms of CRS or neurologic toxicity, including ICANS, occur.
- Monitor patients for signs or symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive therapy based on severity. Withhold or permanently discontinue **TECVAYLI** or **TALVEY** 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, neurologic toxicity, and ICANS, refer to the **Prescriber Training Program** and the **Adverse Reaction Management Guide**.

TECVAYLI and TALVEY REMS FACT SHEET

Key Requirements of the TECVAYLI and TALVEY REMS

Healthcare providers who prescribe TECVAYLI and/or TALVEY



Receive training on the REMS requirements at www.TEC-TALREMS.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** and/or **TALVEY** 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 step-up dosing schedule.

Pharmacies and Healthcare Settings that dispense TECVAYLI and/or TALVEY



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

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



Authorized Representatives must be trained at www.TEC-TALREMS.com using the *Pharmacy and Healthcare Setting Training Program*.



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



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

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** or **TALVEY** step-up dosing schedule.

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.

Healthcare providers should report all suspected adverse events or product quality complaints to Janssen at 1-800-Janssen (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Important Program Updates



The **TECVAYLI REMS** is now called the **TECVAYLI and TALVEY REMS**.

Prescribers

- New prescribers must be certified in the **TECVAYLI and TALVEY REMS** to treat patients with **TECVAYLI** or **TALVEY**. Learn more [here](#).
- For prescribers that are certified in the **TECVAYLI REMS**, certification will automatically be transferred to the **TECVAYLI and TALVEY REMS**.
- Prescribers must review each product's drug's USPI, the *Adverse Reaction Management Guide* and the *Prescriber Training Program*.

Pharmacies and Healthcare Settings

- New pharmacies and healthcare settings must be enrolled in the **TECVAYLI and TALVEY REMS** to dispense **TECVAYLI** or **TALVEY** to patients. Learn more [here](#).
- Pharmacies and healthcare settings previously certified in the **TECVAYLI REMS** will have their enrollment transferred to the **TECVAYLI and TALVEY REMS**.
- Authorized Representatives will be required to complete a re-attestation in the REMS before purchasing and dispensing **TALVEY**. Pharmacies and Healthcare Settings will be able to continue purchasing and dispensing **TECVAYLI** prior to completing their re-attestation.
- To re-attest online, please [login](#) or contact the REMS for further assistance by calling 1-855-810-8064.

Close



TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS)

TECVAYLI and TALVEY REMS

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

- Ensuring prescribers are aware of the importance of monitoring for the signs and symptoms of CRS and neurologic toxicity, including ICANS, in patients exposed to TECVAYLI or TALVEY.

Prescribers	Pharmacies and Healthcare Settings
Prescribers must be certified in the TECVAYLI and TALVEY REMS to treat patients with TECVAYLI or TALVEY.	Pharmacies and Healthcare Settings must be enrolled in the TECVAYLI and TALVEY REMS to dispense TECVAYLI or TALVEY to patients.
Learn More	Learn More

What is the TECVAYLI and TALVEY 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 TECVAYLI and TALVEY outweigh the risks of CRS, neurologic toxicity, and ICANS.

Indications

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.

TALVEY is a bispecific GPRC5D-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

Reporting of suspected adverse events after administration of therapy is vital for the continued monitoring of the risk/benefit balance of therapy.

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.

Healthcare providers should report all suspected adverse events or product quality complaints to Janssen at 1-800-Janssen (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Have Questions?

Contact the TECVAYLI and TALVEY REMS by calling 1-855-810-8064.

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 or TALVEY 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 or TALVEY treatment and when to contact the patient's oncologist.

[Patient Wallet Card](#)



Prescribers

TECVAYLI and TALVEY REMS Requirements

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

How do I become certified in the TECVAYLI and TALVEY REMS?

- Step 1:** Have the Prescriber review the following materials:

[Prescriber Training Program](#) [Adverse Reaction Management Guide](#)
- Step 2:** Have the Prescriber successfully complete the [Knowledge Assessment](#) and submit it to the REMS program
- Step 3:** Have the Prescriber complete the [Prescriber Enrollment Form](#) and submit it to the REMS program
- 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](#). 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 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 and TALVEY REMS Requirements

All Pharmacies and Healthcare Settings involved in the dispensing of TECVAYLI or TALVEY must enroll in the TECVAYLI and TALVEY REMS.

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

- 1** **Step 1:** Designate an Authorized Representative for the Pharmacy and Healthcare Setting
- 2** **Step 2:** Have the Authorized Representative review the [Pharmacy and Healthcare Setting Training Program](#)
- 3** **Step 3:** Have the Authorized Representative complete the [Pharmacy and Healthcare Setting Enrollment Form](#) and submit it to the REMS
- 4** **Step 4:** Train all relevant staff involved in dispensing TECVAYLI and/or TALVEY on the REMS requirements using the [Pharmacy and Healthcare Setting Training Program](#)

Resources for Pharmacies and Healthcare Settings

[Download Pharmacy and Healthcare Setting Enrollment Form](#)

[Download Pharmacy and Healthcare Setting Training Program](#)

[Download All Pharmacy and Healthcare Setting Resources](#)



Pharmacy and Healthcare Setting Enrollment

TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS)

Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified to dispense, pharmacies and healthcare settings must 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.
- Review the **Pharmacy and Healthcare Setting Training Program**.
- Complete this **Pharmacy and Healthcare Setting Enrollment Form**:
 - Online at www.TEC-TALREMS.com for immediate enrollment
 - by e-mail at TEC-TAL@JanssenREMS.com, or
 - via fax to 1-877-588-7823.
- TECVAYLI and TALVEY are currently available to limited pharmacies and healthcare settings. Completion of this form does not guarantee your Pharmacy or Healthcare Setting will be authorized to purchase TECVAYLI or TALVEY.
- The TECVAYLI and TALVEY REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and provide confirmation of certification via e-mail after processing.
- TECVAYLI and/or TALVEY cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

Prescribers certified in the TECVAYLI and TALVEY REMS 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

Pharmacy and Healthcare Setting Enrollment

TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS)

Pharmacy and Healthcare Setting Enrollment Form

Instructions

- To become certified to dispense, pharmacies and healthcare settings must 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.
 - Review the **Pharmacy and Healthcare Setting Training Program**.
 - Complete this **Pharmacy and Healthcare Setting Enrollment Form**:
 - Online at www.TEC-TALREMS.com for immediate enrollment
 - By e-mail at TEC-TAL@JanssenREMS.com, or
 - via fax to 1-877-696-7623.
 - TECVAYLI and TALVEY are currently available to limited pharmacies and healthcare settings. Completion of this form does not guarantee your Pharmacy or Healthcare Setting will be authorized to purchase TECVAYLI or TALVEY.
 - The TECVAYLI and TALVEY REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and provide confirmation of certification via e-mail after processing.
 - TECVAYLI and/or TALVEY cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.
- Prescribers certified in the TECVAYLI and TALVEY REMS 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#)

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

*Pharmacy/Healthcare Setting Name

*Stakeholder Type
 Pharmacy Healthcare Setting

DEAF (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
 Specialty Pharmacy Other (please specify)

*Address Line 1 Address Line 2

*City *State *Zip Code

*Phone *Fax

Ship To Information

*Ship To Contact Name

Shipping Address - Same as above

*Address Line 1 Address Line 2

*City *State *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**.
 - Enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS.
 - Train all relevant staff involved in dispensing TECVAYLI and/or TALVEY on the REMS requirements using the **Pharmacy and Healthcare Setting Training Program**.
 - Oversee implementation and compliance with the REMS requirements on behalf of the Pharmacy and/or Healthcare Setting.
- Before dispensing, staff must:
- Obtain authorization to dispense each prescription by contacting the 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 REMS.
 - Not distribute, transfer, loan or sell TECVAYLI and/or TALVEY except to certified pharmacies and healthcare settings.
 - Maintain records of staff training.
 - Maintain records that processes and procedures are in place and are being followed.
 - Maintain records of all TECVAYLI and TALVEY dispenses and provide data to the REMS and Wholesaler-Distributor, as requested.
 - 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.
 - Have a new Authorized Representative enroll in the REMS by completing and resubmitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS if the Authorized Representative changes.

*Authorized Representative e-signature

*Authorized Representative Attestation

[Please note that the e-signature functionality will be available within 60 days of approval of the TECVAYLI and TALVEY REMS.]

Clear Cancel Submit

Pharmacy and Healthcare Setting Enrollment

TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS) Pharmacy and Healthcare Setting Enrollment Form

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*Enrollment Type (Please Check One)
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*Pharmacy/Healthcare Setting Name

*Stakeholder Type
 Pharmacy Healthcare Setting

DEAR (on file with distributor account) HIN

*Pharmacy/Healthcare Setting Type (Select one)
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 Oncology Infusion Center Community Oncology Physician Office
 Specialty Pharmacy Other (please specify)

*Other Pharmacy/Healthcare Setting Type

*Address Line 1 Address Line 2

*City *State *Zip Code

*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 RPh RN
 Other (please specify: e.g., MD, DO, Office Administrator, Practice Manager)

*Other Credentials

*Phone *Fax *e-mail

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*Authorized Representative e-signature

*Authorized Representative Attestation

[Please note that the e-signature functionality will be available within 60 days of approval of the TECVAYLI and TALVEY REMS.]



Pharmacy and Healthcare Setting Enrollment

Thank you for submitting your information to enroll in the TECVAYLI and TALVEY 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 and TALVEY REMS at 1-855-810-8064.

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 **TECVAYLI**[®]
(teclistamab-cqyv) Injection for
subcutaneous use
10 mg/mL and 90 mg/mL

 **TALVEY**[™]
(talquetamab-tgvs) Injection for
subcutaneous use
2 mg/mL and 40 mg/mL

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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
08/09/2023 06:06:28 PM