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

WHAT YOU'LL NEED TO KNOW BEFORE YOUR TECVAYLI® and TALVEY® REMS AUDIT

As part of the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS) requirement, Janssen is required to conduct audits of certified Pharmacies and Healthcare Settings (HCS) within 120 calendar days after receiving their first shipment of TECVAYLI® or TALVEY®, and annually thereafter. This is to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. This guide will help you be audit ready.

How can your Pharmacy or HCS be audit ready?

☐ Policies and Procedures:
- Create policies and procedures that are readily available, described adequately, and contain specific language regarding the following*:
  - TECVAYLI® and TALVEY® are only dispensed after obtaining a REMS Dispense Authorization (RDA) from the REMS program, which verifies that each prescription is written by a certified prescriber
  - TECVAYLI® and TALVEY® are not distributed, transferred, loaned, or sold except to certified Pharmacies and HCS*
  - Reporting of any serious Adverse Events† suggestive of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- Ensure procedure is in place to report any changes in the Authorized Representative (AR) by having the new AR contact the REMS Coordinating Center (CC)

☐ Training:
- Train all relevant staff involved in the dispensing of TECVAYLI® and/or TALVEY® on the requirements and processes of the TECVAYLI® and TALVEY® REMS using the Pharmacy and Healthcare Setting Training Program
- Create and actively maintain training records (Training Log) for all staff involved in the dispensing of TECVAYLI® and/or TALVEY®
- Training Logs should include date, name, and title of training

☐ Dispense Records:
- Create and actively maintain TECVAYLI® and/or TALVEY® Dispense Records (Dispensing Log) for your Pharmacy or HCS. The dispensing log should be in a format that can readily generate a report from the full data set as needed
- Ensure Dispense Records include the following:
  - First and last name of the prescriber
  - Dispense date and product name

*Include product or drug class as appropriate.

†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.

Any previous REMS policies and procedures for TECVAYLI® should be updated to now include both TECVAYLI® and TALVEY®

For more information about the TECVAYLI® and TALVEY® REMS, including complete US Prescribing Information, please visit www.TEC-TALREMS.com

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The Audit Process

The Pharmacy and Healthcare Settings (HCS) Audit Questionnaire (AQ) and supporting documentation must be completed by the Authorized Representative (AR) or Delegate for the certified Pharmacy and HCS site within 45 calendar days of receipt. Completion of the audit questionnaire is a requirement of the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS) to ensure all processes and procedures are in place and functioning to support the requirements of the TECVAYLI® and TALVEY® REMS. Failure to complete the audit will result in de-certification of your Pharmacy or HCS, and your Pharmacy or HCS will no longer be able to purchase or dispense TECVAYLI® and/or TALVEY®.

1. Quality Assurance (QA) Audit Team emails audit questionnaire to AR

- Day 1 Audit Notification emailed to AR and Delegate by Quality Assurance (QA) Audit Team
- Day 3–5 (business): Reminder call from QA Audit Team
- Day 20 (calendar): Reminder email notification from QA Audit Team
- Day 35 (calendar): Reminder notification from QA Audit Team if the AQ and supporting documentation have not been returned
- Day 40 (calendar): Final notification alerting the AR and Delegate they have 5 calendar days to complete and return the AQ and supporting documentation

2. AR or Delegate submits the completed audit questionnaire and supporting documentation

Completion of the AQ and supporting documentation is required within 45 calendar days of receipt. Identify any situations where the criteria (see previous page) were not met during the audit period and prepare documentation to list the non-compliances, provide rationale, and describe what corrective actions were taken. If no corrective actions were taken, take appropriate corrective action now and document.

- Within 45 calendar days of receipt of Audit Notification: Pharmacy and HCS AR or Delegate will log into their REMS Portal and complete the AQ and provide ALL requested supporting documentation. The completed AQ should include identification of noncompliances and corrective actions taken.

If AR or Delegate does not submit completed AQ and supporting documentation to QA Audit Team by Day 45 (calendar), Janssen will determine appropriate action, which may include de-certification of Pharmacy or HCS.

3. Audit Team performs review within 10 business days of receipt of the AQ and supporting documentation

Further Action Required

QA Audit Team requests additional information

AR or Delegate submits additional information in 5 business days

NON-COMPLIANT

QA Audit Team reviews additional information and determines Pharmacy or HCS to be non-compliant.

QA Audit Team sends notification email with non-compliance identified and provides Janssen Corrective and Preventive Actions (CAPA) Form to Pharmacy or HCS AR to complete and institute‡ within 30 business days of receipt.

COMPLIANT

COMPLIANT

QA Audit Team determines Pharmacy or HCS to be compliant and a completion notification is sent at the conclusion of the audit.

Failure to comply with the CAPA for TECVAYLI® and TALVEY® REMS requirements could result in decertification.

For additional information on TECVAYLI® and TALVEY® REMS, please visit www.TEC-TALREMS.com or call the REMS Coordinating Center at 1-855-810-8064, Monday–Friday, 8AM–8PM ET.

‡The AR is responsible for all remediation activities.

<PRODUCT> Training Log

Logs below are for reference purposes and reflect the data fields required to comply with REMS training and the dispense record requirement. You may use your own internal modalities for documentation purposes. The use of these logs is optional.

This sign-in sheet documents that all personnel listed below have completed the required training.

Training Title and Description	Version	Document Reference(s) (if applicable)
Title: *<Title of Training Program>*	#_____	*<Title of Training Program>* Current Training : *<PRODUCT Website>*

Training Date	Employee Name	Title

<PRODUCT> Dispense Log

Treatment/Dispense Date	Drug Name	Prescriber Full Name	Notes