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, Johnson & Johnson is required to conduct audits of certified Pharmacies and Healthcare Settings (HCS) within 180 calendar days after receiving their first shipment of TECVAYLI® or TALVEY®, and annually from the date of the last audit initiation. 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?

☐ Ensure a procedure is in place to report any changes in the Authorized Representative (AR) by having the new AR contact the REMS Coordinating Center (CC).

☐ **Processes and Procedures:**

- Create a processes and procedures document that is readily available and contains 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) to the REMS program
  - Both TECVAYLI® and TALVEY® or the drug class must be referenced in the processes and procedures, even if only one product is dispensed

☐ **Training:**

- Train all relevant staff involved in the dispensing of TECVAYLI® and TALVEY® on the requirements 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 TALVEY®
- Training Logs should include date, name, and title of training (*TECVAYLI® and TALVEY® REMS Pharmacy and Healthcare Setting Training Program*)

☐ **Dispensing:**

- Create and actively maintain TECVAYLI® and/or TALVEY® dispense records (Dispensing Log) for your Pharmacy or HCS
- Ensure Dispensing Logs include the following:
  - First and last name of the prescriber
  - Dispense date and product name
  - RDA Code, as available

*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.

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

To connect with a Safety Program Advisor (SPA) for REMS education and operational support, please email REMSProgramAdvisor@its.jnj.com.

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The Audit Process

1

The Pharmacy and HCS Audit Questionnaire (AQ) and supporting documentation must be completed by the AR or Delegate for the certified Pharmacy or HCS site within **30 calendar days of receipt.**

Completion of the AQ is a requirement of the TECVAYLI® and TALVEY® REMS.

2

The AQ must be submitted within 30 calendar days of receipt. The REMS Audit Team will send reminders to the AR to complete the AQ and provide any missing documentation. Failure to complete the audit will result in decertification of your Pharmacy or HCS on day 31, and your Pharmacy or HCS will no longer be able to purchase or dispense TECVAYLI® or TALVEY®.

3

The REMS Audit Team performs review within 5 business days of receipt of the AQ and supporting documentation. The REMS Audit Team may request additional information, which the AR must submit within 7 calendar days.

4

If the REMS Audit Team determines the Pharmacy or HCS to be compliant, they will email a notification of successful audit completion within 2 calendar days of review.

If the REMS Audit Team determines the Pharmacy or HCS to be non-compliant, they will email a notification with a non-compliance identified and, as applicable, provide the J&J Corrective and Preventative Actions (CAPA) Form to complete and institute within 30 calendar days of receipt.

The AR is responsible for all remediation activities.

Failure to comply with the Audit and any associated CAPA requirements could result in decertification.

Decertified sites are unable to purchase or dispense TECVAYLI® or TALVEY®.

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.

<PRODUCT> Training Log

Logs below are for reference purposes and reflect the data fields required to comply with REMS training and the dispensing 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> Dispensing Log

Treatment/Dispense Date	Drug Name	Prescriber Full Name	Notes