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

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 must be trained on the REMS requirements using this Pharmacy and Healthcare Setting Training Program.

Johnson&Johnson

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TECVAYLI and TALVEY REMS

www.Tec-TalREMS.com

Phone: 855-810-8064

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:
  - in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
  - as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Indications

- **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
- Establish processes and procedures to identify prescriptions written by a prescriber who has not had a TECVAYLI or TALVEY prescription filled by the pharmacy or healthcare setting before
- Before dispensing:
  - Identify prescriptions written by a prescriber who has not had a TECVAYLI or TALVEY prescription filled by the pharmacy or healthcare setting before through the processes and procedures established as a requirement of the REMS
  - For prescriptions written by a prescriber who has not had a TECVAYLI or TALVEY prescription filled by the pharmacy or healthcare setting before: Obtain authorization to dispense by contacting the REMS Program 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.

Delegate Role

- One Delegate may be added to support the Authorized Representative at each Pharmacy and Healthcare Setting with staff management and audit completion.
- The Authorized Representative is responsible for overseeing all activities performed by the Delegate in the TECVAYLI and TALVEY REMS.
- A Delegate can be:
  - A Licensed Pharmacist
  - A Pharmacy Technician
  - A Registered Nurse
  - Any responsible individual assigned by the AR

Managing Pharmacy and Healthcare Setting Staff

- The Authorized Representative (AR) or Delegate may grant Pharmacy and Healthcare Setting Staff access via the *Staff Management* tab in the TECVAYLI and TALVEY REMS Portal
- Once the Authorized Representative or Delegate 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

- **Establish processes and procedures to identify prescriptions written by a prescriber who has not had a TECVAYLI or TALVEY prescription filled by the pharmacy or healthcare setting before**
- **The first prescription of TECVAYLI and/or TALVEY received from a prescriber that has not had a prescription of TECVAYLI or TALVEY filled by your pharmacy or healthcare setting before may only be dispensed upon generation of a REMS Dispense Authorization (RDA) code**
- To generate an RDA code, the Authorized Representative (AR), Delegate, or designated staff will log into the TECVAYLI and TALVEY REMS portal at **www.TEC-TALREMS.com**
  - First, select the **"RDA/Prescriber Certification Check"** tab
  - After selecting TECVAYLI or TALVEY, enter the ordering Prescriber's NPI# or name, select the prescriber, and clicking on the "Generate Authorization Code" button,
  - One of the following messages will appear:
    - **DO NOT DISPENSE**
    - **OK TO DISPENSE**
      - The RDA code will display for documentation purposes
- The AR, Delegate, or designated staff may also contact the TECVAYLI and TALVEY REMS Coordinating Center via phone at 1-855-810-8064 to obtain an RDA code
- **You do not need to verify prescriber certification for a known prescriber's subsequent prescriptions**
- Maintain records of all TECVAYLI and TALVEY dispenses 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 the REMS Program at 1-855-810-8064
- Pharmacy and Healthcare setting staff should report all suspected adverse events or product quality complaints to Janssen Biotech, Inc., a Johnson & Johnson Company at 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*

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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**.

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