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***.

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PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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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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.

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For more information, to enroll in the **TECVAYLI and TALVEY REMS**, and for all REMS materials go to **www.TEC-TALREMS.com**.