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 are two distinct products with differences in dosing and administration, safety, and use.

INITIATING STEP-UP DOSING WITH BISPECIFICS

Expanding an existing bispecifics operational model to include step-up dosing (SUD) requires specific adjustments and additional considerations. Completed steps such as REMS certifications and adverse reaction (AR) management protocols are foundational to the operational model. This checklist is designed for sites that already have infrastructure in place from administering treatment dosing for TECVAYLI and/or TALVEY and that wish to build upon their model to initiate step-up dosing. This is not intended to be a comprehensive list, and individual practices should follow their own required procedures.

Existing Bispecifics Operational Lead:

Quick Tip: Leverage EHR to Identify Eligible Patients
It's essential to identify new therapeutic approaches as patients with RRMM progress through lines of therapy and have fewer treatment options. Leverage patient list EHR build guides to identify patients who may be eligible for bispecific therapy.

1 Adapt existing adverse reaction protocols to set up for step-up dosing*

- ☐ Define prophylaxis and pretreatment protocols to help reduce the risk of specific ARs when initiating treatment
- ☐ Ensure the site's repository of AR management protocols is up to date
- ☐ Develop clear escalation pathways and obtain authorization for supportive therapies in the event of ARs

* Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of each TALVEY step-up dose. Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of both TECVAYLI step-up dose 1 and step-up dose 2; instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI step-up dosing schedule.

Quick Tip: Refer to additional protocol resources* to support your providers and care team, including:

IMWG Consensus Guidelines and Recommendations for Optimal Use of T-cell-Engaging Bispecific Antibodies in Multiple Myeloma[1]

Click to View

Data rates may apply.

NCODA Immunotherapy Hub Example SOPs and Documents[2]

Click to View

Data rates may apply.

*The links to resources above may contain data, conclusions, and recommendations that do not conform to the FDA-approved labeling for bispecific therapies from Johnson & Johnson. The opinions expressed in the links above do not necessarily reflect those of Johnson & Johnson. Bispecific therapies from Johnson & Johnson should be used only as specified in the Prescribing Information.

2 Expand and reinforce care team training to ensure confidence in managing step-up dosing

- ☐ Deploy existing bispecifics training to the broader care team and specialists (eg, ED, hospitalists, neurologists) who may be involved in step-up dosing administration, monitoring, and AR management
- ☐ Ensure new prescribers are REMS certified
- ☐ Train core staff and ancillary support on new SUD protocols
- ☐ Maintain a plan for periodic new hire and refresher training

Refresher training will be completed every **6 Months**

3 Ensure your patients and their care partners are prepared as they initiate the bispecific treatment journey

- ☐ Develop a patient-specific treatment plan, including:
  - Dosing schedules
  - Site(s) of administration and treatment transitions (if applicable)
  - Prophylaxis procedures for ARs such as CRS, neurologic toxicity including ICANS, infections (eg, VZV and PJP), neutropenia, hypogammaglobulinemia, and VTE (thromboembolism)
  - Escalation procedures
- ☐ Complete the Patient Wallet Card and give it to the patient to carry at all times, designating their treatment status to an ED or other HCPs in an emergency
- ☐ Educate on treatment expectations, including information on the therapy, AR monitoring and plans of action, logistical support, and/or financial considerations

will be the primary person responsible for education of the patient and care partner.

Deeper Dive: Determining the appropriate treatment plan for each patient often includes the measures described below. Use a treatment locator to help find and engage nearby certified physicians who already administer step-up dosing for insights and consider approaches to patient monitoring.

- **Coordinating with the healthcare team and the patient to develop a plan for hospital monitoring and to schedule step-up dosing**
- **Defining the individual patient plan for monitoring after each step-up dose**
- **Ensuring specialists and an on-call physician are prepared in the event of ARs**
- **Continuously monitoring the patient for ARs for 48 hours following administration of each step-up dose***
- **Confirming authorization of SUD doses and site of administration approval with regard to financial considerations**

*Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of each TALVEY (talquetamab-tgvs) step-up dose. Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of both TECVAYLI (teclistamab-cqyv) step-up dose 1 and step-up dose 2; instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI step-up dosing schedule.

Data rates may apply.

The Johnson & Johnson ABS team is here to help operationalize TECVAYLI and TALVEY across community clinics by identifying operational and economic considerations, providing education to address barriers to treatment, and simplifying processes to support pharmacists, practice managers, and clinical staff.

You can also scan the QR code to visit BispecificsGuide.com for more information on preparing your treatment site.

ABS, area business specialist; APP, advanced practice provider; CRS, cytokine release syndrome; ED, emergency department; EHR, electronic health records; HCP, healthcare provider; ICANS, immune effector cell-associated neurotoxicity syndrome; IMWG, International Myeloma Working Group; NCODA, Network for Collaborative Oncology Development & Advancement; PJP, Pneumocystis jirovecii pneumonia; REMS, Risk Evaluation and Mitigation Strategies; RRMM, relapsed or refractory multiple myeloma; SUD, step-up dosing; VTE, venous thromboembolism; VZV, varicella-zoster virus.

References: 1. International Myeloma Working Group Immunotherapy Committee. International Myeloma Working Group immunotherapy committee consensus guidelines and recommendations for optimal use of T-cell-engaging bispecific antibodies in multiple myeloma. *Lancet Oncol.* 2024;25(5):e205-e216. **2.** Immunotherapy hub. NCODA. Accessed April 3, 2026. https://www.ncoda.org/immunotherapy-hub/

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