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 TREATMENT DOSING WITH BISPECIFICS

Operationalizing treatment dosing—ongoing treatment following the initial step-up dosing period—requires several steps unique to bispecifics. Many activities for establishing outpatient treatment are similar to those of other RRMM therapies (eg, patient education, drug procurement, billing and coding). This checklist focuses on the unique core requirements for sites preparing to begin administering treatment dosing for TECVAYLI or TALVEY. This is not intended to be a comprehensive list, and individual practices should follow their own required procedures.

Quick Tip: Identify an operational champion to facilitate key activities for your multidisciplinary team.

1 | Complete REMS

Click for More Information

Enroll your pharmacy or healthcare site

- ☐ Designate an authorized representative for the pharmacy and healthcare setting
- ☐ Have the authorized representative review the Pharmacy and Healthcare Setting Training Program
- ☐ Have the authorized representative complete the Pharmacy and Healthcare Setting Enrollment Form and submit it to the REMS
- ☐ Train all relevant staff involved in dispensing TECVAYLI and/or TALVEY on the REMS requirements using the Pharmacy and Healthcare Setting Training Program

Become a certified prescriber

- ☐ Review the Prescriber Training Program and Adverse Reaction Management Guide
- ☐ Complete the REMS Knowledge Assessment and submit it to the REMS program
- ☐ Complete the Prescriber Enrollment Form and submit it to the REMS program

Audit Preparation: Standardized documentation processes can encourage organizational continuity and help ensure preparedness for future audits.

2 | Establish adverse reaction protocols

- ☐ **Ensure that providers are familiar with product adverse reaction (AR) profiles. Risks include:**
  - CRS
  - Neurologic toxicity (including ICANS)
  - Additional ARs (both hematologic and nonhematologic)
- ☐ **Tailor your monitoring and management protocols, including:**
  - Define patient monitoring protocols
  - Develop a centralized repository of treatment protocols and algorithms for toxicity management
  - Establish an on-call physician to help manage CRS and neurotoxicity, including ICANS
- ☐ **Deploy stakeholder information**
  - Train staff on protocols and maintain a plan for periodic new hire and refresher training
    6 Months
  - Educate patients on prevention and monitoring for typical or opportunistic infections
  - Educate patients and care partners on AR monitoring and what to do in case of an emergency

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.

3 | Align with collaborating sites of care

- ☐ Identify certified site(s) for step-up dosing that can return patients to your center for ongoing treatment
- ☐ Identify local hospital/emergency department partners to ensure there is readiness in the event of ARs during treatment
- ☐ Coordinate with the initiating treatment center to determine when the patient will return to the community site for ongoing treatment
- ☐ Define roles, responsibilities, and logistics for the patient transfer back to your center
- ☐ *Fill in the organization names, HCP contacts, and phone numbers of collaborating hospitals/EDs and initiating treatment sites below*

Consider the following measures when establishing supportive care sites:
- Ensure the ED/hospitalists are aware that your site will be administering treatment and provide contact information for your treatment site's on-call physician
- Consider sharing product AR management guides with partner hospitals/EDs
- Note that supportive sites of care do not need REMS certifications to manage potential patient ARs
- Ensure the patient always carries their Patient Wallet Card to designate their treatment status to an ED or other HCPs in an emergency

Use a treatment locator to help find nearby certified physicians who have indicated that they administer step-up dosing, or work with an existing collaborating site of care

Leverage patient list EHR build guides to identify appropriate patients who may be eligible for bispecific therapy and work with your collaborating site to initiate treatment

Consider the following variables when coordinating with the initiating treatment center to determine the patient's return:
- Plans for follow-up care, patient check-ins, and site readiness for scheduling continuing treatment
- Site-of-care economic considerations for the SUD site
- Documentation for insurance reauthorization of the next treatment dose to ensure a seamless transition
- Severity of any adverse reactions experienced by the patient during step-up dosing

Develop a memorandum of understanding to formally help define responsibilities and logistics for the patient transfer

Data rates may apply.

The Johnson & Johnson ABS team is here to help operationalize TECVAYLI (teclistamab-cqyv) and TALVEY (talquetamab-tgvs) 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; REMS, Risk Evaluation and Mitigation Strategies; RRMM, relapsed or refractory multiple myeloma; SOPs, standard operating procedures; SUD, step-up dosing.

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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