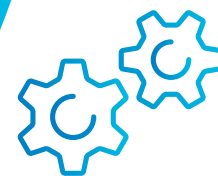


Operational Considerations to Assess and Build Outpatient Bispecific T-cell Engager Therapy Capability



This operational considerations list has been developed to help cancer centers adopt the use of Bispecific T-cell Engager therapies.

The information provided herein is intended to help provide operational considerations when administering Bispecific T-cell Engager therapies. The considerations below are for general informational purposes only, and it is the responsibility of the healthcare provider to refer to the recommendations in specific product labeling as applicable.

MULTIDISCIPLINARY CARE TEAM

Determine members of the multidisciplinary team that will be involved in the administration of the Bispecific T-cell Engager therapy, monitoring, and patient care

- Examples of potential care team members and responsibilities are below
- Ensure multidisciplinary care team members are trained in the requirements to safely treat post-therapy patients with Bispecific T-cell Engager therapies¹

HEALTHCARE AND THERAPY TEAM



Advanced Practice Provider (APP*)



Social Worker



Care Coordinator



Pharmacist



Medical Oncologist/Hematologist



Registered Nurse (RN)



Access Specialist



Other (ICU, ER Staff, Other Specialists[†])

- Identify main points of contact who are the primary resource for logistics and coordination of multidisciplinary care team

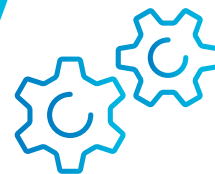
LOGISTICS & INSTITUTIONAL CAPABILITIES

- **Assess logistic and capability requirements for the following:**
 - Accessibility of sufficient chair time per patient to ensure that all pre-treatment(s), Bispecific T-cell Engager therapy administration, long post-therapy monitoring (depending on specific Bispecific T-cell Engager therapy and prior treatment exposure), and patient discharge can occur within clinic operational hours
 - Pharmacy capability to prepare and dispense Bispecific T-cell Engager therapy and supportive care medications based on product label or institutional guidelines
 - Availability of ancillary delivery equipment (eg, ambulatory infusion pumps, tubing, bags, IV solution) that may be required within the product label¹
 - Fulfillment of staffing needs (eg, nurse, dedicated APP, pharmacist) if extended monitoring is required for Bispecific T-cell Engager therapy

*May include clinical nurse specialists, nurse practitioners, or physician assistants.

[†]May include cardiology, nephrology, infectious diseases, pulmonary/critical care, or neurology.

Operational Considerations to Assess and Build Outpatient Bispecific T-cell Engager Therapy Capability (continued)



LOGISTICS & INSTITUTIONAL CAPABILITIES (CONTINUED)

- **Identify hospital and their points of contact for emergency/urgent care, step-up (ICU), or inpatient admission, considering any proximity requirements based on product label**
 - Consider staff education/collaboration on adverse event management and ability to maintain consistent communication with multidisciplinary care team¹
 - Confirm process to ensure that all institutions involved in patient care have access to patients' medical information¹
 - Through the same EMR system (if the institutions are affiliated), or
 - Through external record-sharing (if not affiliated)
- **Develop or adapt existing treatment and toxicity management algorithms and standard operating procedures to consider the following:**
 - Administration of Bispecific T-cell Engager therapy in an outpatient setting, if applicable based on manufacturer labeling
 - Verify clinic/staff ability to follow patient throughout treatment cycle, considering frequency and type (in-person/phone/virtual) of follow-up
 - Determine if you'll need to procure and administer any premedication, concomitant medication, and supportive medications, monitor toxicity, implement relevant work-ups, and provide/develop guidelines for treating complications (adverse event management)^{1,2}
 - Incorporate adverse event assessment according to product label or institutional policy
 - Develop instructions for patient transport from clinic or home to appropriate site of escalated care¹
 - Identify home healthcare service to facilitate home infusion or monitoring, as needed¹
 - Develop a plan for how patients will be monitored in the outpatient setting¹
 - If home monitoring devices are needed, develop protocols for use of digital health technology¹
 - Provide appropriate patient coverage deployment to review/acknowledge alerts and vital signs, and conduct any necessary follow-ups
- **Develop a plan for patient and caregiver education on**
 - Length and frequency of clinic visits
 - Bispecific T-cell Engager therapy administration
 - Post-therapy monitoring in clinic and at home, if necessary
 - Potential adverse events after discharge—how/when to seek help (including possible hospitalization)¹
 - Home health and/or ambulatory pump, if applicable

EMR, electronic medical record; ER, emergency room; ICU, intensive care unit; IV, intravenous.

References: **1.** Association of Community Cancer Centers. https://www.accc-cancer.org/docs/projects/bispecificantibodies/checklist-for-bispecific-antibodies-jan-2022.pdf?sfvrsn=ad2f3ee4_2. Accessed April 16, 2024. **2.** Shimabukuro-Vornhagen A, et al. *J Immunother Cancer*. 2018;6:56.