Oncology Provider/Physician Considerations for Implementing Bispecific T-cell Engager Therapies

This Provider/Physician 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.

BEFORE TREATMENT (PRIOR TO FIRST DOSE)

- **Determine whether patient's condition meets the approved use per product label for the particular Bispecific T-cell Engager therapy and whether use is clinically appropriate**
- **Assess potential access and coverage issues (ie, prior authorization) for the patient**
- **Consult the package insert and guidelines for each individual therapy to determine a detailed treatment plan**
  - Communicate the treatment plan to all relevant stakeholders (eg, nurses, Clinical Pharmacist, Advanced Practice Provider), patients/caregivers, and ancillary staff [ED, ICU])
  - Consider any premedications, concomitant medications, or other treatments for nurse and pharmacy review[1,2]
  - Consider laboratory parameters and/or testing that may be required for treatment and monitoring[1]
  - Check if there are any needs for ambulatory infusion pump based on the product label[3]
  - Assess whether the patient has support of a home caregiver who will cohabitate with the patient for a length of time as deemed appropriate[3]
  - Consider discussing with your nursing and pharmacy staff:
    - Adverse event management instructions (eg, signs/symptoms and parameters to administer each supportive medication)[3]
    - When a provider should be contacted or when escalation of care is needed[3]
  - Check the product label for monitoring parameters to be assessed during Bispecific T-cell Engager therapy administration, after therapy, and upon discharge from the clinic
  - Consider where potential toxicities based on the product label should be managed, whether at a community cancer center or academic center (eg, when should a patient be admitted to an academic center)[3]
  - Determine where patients should be hospitalized if the need arises (considering distance from the clinic and/or patient's home)[3]
- **Educate the clinical staff (clinic, ED, ICU) based on the product label about the specific medication administration, side effects, and other relevant information, including**
  - Potential infusion requirements relating to an infusion pump, flushing of an infusion line, etc based on the product label[3]
  - Any monitoring parameters and management of emergent side effects and other adverse event–related specifics[3]
  - Clinic time needs for therapy administration and monitoring[3]
  - Whom to contact for medical emergencies[3]
- **Consider establishing a post-treatment follow-up schedule per the product label/manufacturer's recommendations**
  - Consider whether follow-up care should be in-person, via phone, or virtual[3]

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DURING TREATMENT ADMINISTRATION (DAY OF INFUSION)

- **Monitor patients for signs and symptoms of potential toxicities and provide appropriate management based on the product label and/or institutional guidelines[2-4]**
- **Check whether dose adjustments, treatment interruptions, or treatment termination are warranted, and reinitiate treatment per manufacturer's recommendations[2]**

POST TREATMENT (EACH CYCLE AND END OF TREATMENT)

- **Consider advising patients/caregivers on:**
  - Monitoring for signs and symptoms of side effects and instructions from healthcare team on when to call or seek immediate assistance[3]
  - The FDA-approved patient labeling
- **Counsel patients/caregivers on the potential adverse reactions with the Bispecific T-cell Engager therapy and associated signs and symptoms based on the product label[3]**
- **Please refer to individual label for patient assessment after therapy**

Report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Amgen at 1-800-772-6436 (1-800-77-AMGEN).

ED, emergency department; ICU, intensive care unit.

References: 1. Einsele H, et al. *Cancer.* 2020;126:3192-3201. **2.** Shimabukuro-Vornhagen A, et al. *J Immunother Cancer.* 2018;6:56. **3.** 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. **4.** Lee DW, et al. *Biol Blood Marrow Transplant.* 2019;25:625-638.

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