Nursing/Clinic Staff Considerations for Implementing Bispecific T-cell Engager Therapies

This Nursing/Clinic Staff 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)

- **Check the product label for any necessary baseline assessments for laboratory parameters and vital signs to determine treatment readiness**
  - Review treatment plan and assess ability to monitor vital signs and laboratory values as necessary per product label and standard protocols
- **Confirm insurance coverage for Bispecific T-cell Engager therapy administration**
- **Assess need for IV access and viability of any existing line**
- **Ensure that premedications or concomitant medications have been ordered, if applicable**[1,2]
- **Schedule necessary chair time, considering scheduling early appointment as close to opening of clinic as possible to accommodate treatment duration and any monitoring requirements based on the product label**
- **Evaluate staffing needs to monitor patient for signs and symptoms of adverse events in outpatient setting**[1]
  - For specific signs and symptoms related to AEs for different Bispecific T-cell Engager therapies, please see the corresponding Bispecific T-cell Engager therapy product label
- **Consider if monitoring requirements will necessitate telehealth, home infusion pumps, and/or digital technology**
- **Consider educating patients/caregivers on expected side effects as indicated in the product label, and provide other safety-related instructions**[1,3,4]
  - Educate patients/caregivers on premedications or concomitant medications, if applicable
  - Provide adverse event monitoring instructions
  - Provide instructions on what to do if adverse events occur *(refer patients/caregivers to patient counseling information in FDA-approved labeling)*
  - Inform patients/caregivers of post-treatment monitoring—in-clinic and/or at home[1]
  - Determine if there's an appropriate caregiver to transport patient as necessary
- **Ensure that adequate support system exists throughout the treatment journey (eg, home medical services, caregivers, transportation, psychological support)**
  - Determine whether patient needs visiting nurse services or social work consultations for additional support, and schedule as appropriate
  - Assess whether the patient has support of a home caregiver who will cohabitate with the patient for length of time, as determined by provider
  - Provide the patient with educational resources on financial assistance

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DURING ADMINISTRATION (DAY OF TREATMENT)

- **Check vital signs and laboratory values to determine if patient meets criteria based on the product label and/or institutional guidelines**
  - Please see the corresponding Bispecific T-cell Engager therapy product label for information on criteria for treatment
- **Check the product label for any premedications that may need to be ordered**[2]
- **Check the product label for dose calculations and follow administration instructions**
  - Follow institutional policy for IV pump usage; ensure use of ambulatory pump when indicated
  - Verify IV admixture label, pump settings, and patient identity before administration
- **Monitor patients for signs and symptoms of potential toxicities per the recommendations in the product label and provide appropriate management**[1,3,4]
- **Check the product label to confirm treatment interruption and re-initiation recommendations**

POST ADMINISTRATION (EACH DOSE)

- **Check the product label for manufacturer's recommendations and/or protocol for post-treatment monitoring (in-clinic and/or at home)**
- **Review follow-up schedule and provide specific contact information**
  - Notify patient/caregiver if any post-treatment monitoring is specifically required based on the product label
  - Plan for follow-up phone calls with patient/caregiver to assess for signs of toxicity or other patient needs
  - Include list of staff members to contact in case of need (eg, medical, technology, home health, social worker, etc.) and specify which members to contact after clinic hours or on weekends
- **Reinforce information with patients and caregivers on potential toxicities to expect with Bispecific T-cell Engager medications and their management**
  - Advise patients/caregivers to contact the designated clinical staff member in case of emergency or to report concerning symptoms based on the product label[1]
  - Assess whether patient has a caregiver to drive patient home from clinic on days of treatment[1]
  - Consider recommendations in product label on hospitalization for potential toxicities[1]
    - Provide patient/caregiver with details of hospital identified for hospitalization, if required for escalated care. Preferred hospital should be identified by oncology provider/physician prior to treatment initiation
- **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)**

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

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