

[Clinic or Hospital Logo]	SOP #	[Number]
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	Owner	[Name]
	Department	[Name]
	Tags	[Tags]
	Applicability	[Name of sites]

Staff Education for Using Bispecific T-Cell Engagers

Where Did This Resource Come From?	
🏥 Clinic/Hospital Type	Mid-sized, partially integrated, community-based clinic
💡 What's Unique?	<ul style="list-style-type: none"> Standardized BTCE education is created for the multidisciplinary team by Clinical Nurse Educators and pharmacists, with annual training and competency evaluations. Integrated documentation ensures adverse event reporting, staff and patient education, and treatment oversight.

1. Purpose

To establish a structured and comprehensive education process for all healthcare personnel involved in the use of bispecific T-cell engagers (BTCE). This SOP ensures that all staff, including physicians, advanced practice providers (APPs), nurses, Clinical Nurse Educators, pharmacists, pharmacy technicians, are adequately trained in the safe and effective use of these therapies. The education program supports patient safety and seamless coordination between the multidisciplinary team.

2. Scope

This SOP applies to all healthcare professionals involved in the administration, monitoring, and coordination of bispecific T-cell engagers across inpatient and outpatient settings. It includes but is not limited to:

- Physicians and Advanced Practice Providers (APPs)
- Oncology and Infusion Nurses
- Clinical Nurse Coordinators
- Pharmacists
- Pharmacy Technicians

3. Definitions

- **Bispecific T-Cell Engager (BTCE):** Synthetic proteins that bind two distinct antigens: one targets the CD3 protein on T cells, and the other targets a specific cancer antigen, redirecting T cells to activate an antitumor immune response.
- **Step-Up Dose:** A dosing strategy that starts with a lower dose and gradually increases it to effectively prime the immune system while minimizing adverse effects.
- **Cytokine Release Syndrome (CRS):** A potentially severe inflammatory response that occurs when immune effector cell therapy leads to the release of cytokines into the bloodstream. This syndrome causes symptoms such as fever, hypotension, hypoxia, chills, tachycardia, dyspnea, nausea, rash, headache, and myalgia.
- **Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS):** A neurological complication caused by inflammation in the central nervous system following immune effector cell therapy. Symptoms can range from mild, such as headache and confusion, to severe, including seizures and coma, which may be life-threatening.
- **Neurotoxicity:** Side effects that impact the nervous system, including those caused by immunotherapy.
- **Risk Evaluation and Mitigation Strategy (REMS):** Risk Evaluation and Mitigation Strategies, required safety protocols for certain medications.

4. Responsibilities

- Pharmacy Technician Supervisor:
 - Trains pharmacy technicians in inventory management, REMS compliance, and coordination of BTCE treatments in collaboration with pharmacists.
 - Orients pharmacy technicians to refer to the prescribing information (PI) for proper storage and handling of BTCEs to ensure adherence to manufacturer recommendations.
- Oncology and Infusion Nurses:
 - Provide education on an overview of BTCE indications, administration, and adverse effects to patients and/or caregivers.
 - Nurse Supervisor trains nurses when hired and retrain per institutional protocols (e.g., annually).
 - Charge nurse trains on-call nursing staff on on-call procedures, including when to contact providers for adverse reactions (e.g., CRS and ICANS management) and how to coordinate with local hospitals in the event patients need inpatient observation.
- Clinical Nurse Educator(s):
 - Develop learning modules that are shareable among staff (including new hires as well as appropriate staff at inpatient and outpatient settings) to provide education on BTCE administration, toxicity management, and emergency response procedures.
 - Establish a process for creating and updating educational materials.
 - Learning modules and educational materials are updated annually and as needed when new therapies, indications, or safety monitoring are released in clinical trials and/or the PI.

- Pharmacists:
 - Provide comprehensive BTCE drug information to pharmacy team and other multidisciplinary team members when hired and as needed to disseminate clinical updates.
 - Collaborate with Clinical Nurse Educator(s) to create institutional educational materials on BTCE therapy.
- Clinic Informatics Team:
 - Train clinic staff on electronic medical record (EMR) alerts and order sets related to BTCE therapy when staff are hired and when new information is updated.

5. Procedure

- Step 1: Creation of Educational Training Materials
 - Pharmacists and Nurse Educator(s) collaborate to create institutional educational materials on BTCE therapy (e.g., FDA approved indications, mechanisms of action, administration, and adverse event management).
 - Determine standardized training frequency for each health care team (e.g., annually).
 - Enroll new hires into Learning Management Systems (LMS).
- Step 2: Initial Staff Training
 - All new employees must complete an initial training module on BTCE therapy, including mechanisms of action, indications, administration, and adverse event management.
 - Training will be conducted via LMS and live in-service sessions (pharmacist manager to educate pharmacy team and Clinical Nurse Educator for nursing team).
- Step 3: Ongoing Staff Education
 - Staff will receive refresher training annually.
 - Updates to treatment protocols, safety guidelines, and new research findings will be disseminated via monthly email bulletins and in-person team meetings.
 - Training platform for LMS will be established to provide online courses for staff.

6. Safety and Compliance Considerations

- REMS Compliance: All sites must adhere to FDA REMS requirements for BTCE.
 - Refer to the Ordering and REMS Compliance SOP.
- Adverse Event Reporting: Staff must report adverse events to the institutional safety team. All clinic staff managers to train staff on how to use the adverse event reporting platform, how to identify adverse events related to BTCEs, and what to report.

7. Records and Documentation

- Maintain log of staff trained in BTCE administration, including dates and trainer names.
- Document staff competency evaluations.
- Ensure staff access to the latest SOP version and document acknowledgements.

- Report, review, and implement mitigation strategies for any administration errors or adverse reactions.

8. References

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9. Revision History

Version #	Date	Description of Changes	Reviewed / Approved By