ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

**DOCUMENT NUMBER:** APBMT-COMM-044

**DOCUMENT TITLE:**
Immune Effector Cell Administration and Patient Management

**DOCUMENT NOTES:**

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**Document Information**

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APBMT-COMM-044
IMMUNE EFFECCTOR CELL ADMINISTRATION
AND PATIENT MANAGEMENT

1 PURPOSE

1.1 To outline the care of the adult and pediatric patient receiving immune effector cells (IECs).

1.2 To describe the processes around IEC administration.

2 INTRODUCTION

2.1 Immune Effector Cells (IEC) are cells used to modulate an immune response for therapeutic intent, such as dendritic cells, natural killer cells, T cells, and B cells. This includes, but is not limited to, genetically engineered chimeric antigen receptor T cells (CAR-T cells) and therapeutic vaccines.

2.2 All staff involved in the prescribing, dispensing, or administration of IEC therapy are required to complete training modules, such as Risk Evaluation and Mitigation Strategy (REMS) specific to each individual product. The knowledge assessment will be kept on file within the Duke Center for Medication Policy.

2.2.1 Training for all staff will include the detection of and management of immune effector cellular therapy complications. See related SOP APBMT-COMM-045 Management of Immune Effector Cell Therapy Complications.

3 SCOPE AND RESPONSIBILITIES

3.1 Interdisciplinary

3.1.1 The physician or physician designee will screen the patient to determine eligibility and place an order for the IEC product and associated supportive care in the electronic medical record (EMR). The physician is ultimately responsible for the care of the patient pre, peri, and post IEC therapy.

3.1.2 The nurse will provide supportive care and administer any treatment ordered by physician.

3.1.3 The pharmacist will ensure availability of medications adequate to treat expected complications of IEC administration.

3.1.4 All staff involved in the care of the immune effector cell patient will be responsible for ongoing monitoring of the patient for complications associated with immune effector cell therapy.

3.1.5 In the event that the primary team deems an escalation of care is needed, patients will be promptly transferred to the care of the intensive care service and will include plans for patient monitoring before, during and after transfer and communication of the ongoing care plan.
4 DEFINITIONS/ACRONYMS
4.1 CRS – Cytokine Release Syndrome
4.2 EMR – Electronic Medical Record
4.3 IECs – Immune Effector Cells
4.4 Licensed personnel – Physician, Advanced Practice Provider, Nurse

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 NA

7 SAFETY
7.1 NA

8 PROCEDURE
8.1 After patient is determined to be an IEC candidate and prior to therapy initiation, there shall be a consultation between the patient and a physician approved to prescribe IEC therapy to review the goal and plan of treatment.

8.2 The patient will be screened by a financial care coordinator and social worker for appropriateness and to ensure adequate resources are in place for treatment.

8.3 The patient, parent and/or legally authorized representative, as applicable, will sign applicable consent(s) as per health system policy and product requirements.

8.4 The patient will receive IEC therapy either on the Adult Hematology Oncology Inpatient Unit (9100), the Pediatric Blood and Marrow Unit (5200) or the corresponding outpatient clinic or infusion rooms.

8.5 The pharmacist and physician will ensure availability of appropriate treatment for cytokine release syndrome (CRS) prior to the initiation of the administration of Immune Effector Cells and during the recovery period.

8.6 The Physician, Advance Practice Provider (APP), or designee will ensure orders are available in the electronic medical record and include premedication and post IV hydration.

8.7 IEC Administration
8.7.1 Patient will be receive premedication 30-60 minutes before the start of the IEC infusion or as per physician orders.

8.7.2 IEC’s will be delivered in a syringe or infusion bag. Tubing will be primed by nursing staff with NS and directly attached to the patient’s central line.
8.7.3 ADULT UNIT PRIMING

8.7.3.1 If the IEC product is prepared in a syringe, connect the syringe containing the product directly to port of the IV tubing that is closest to the patient (lowest port).

8.7.3.2 If the IEC product is prepared in an infusion bag, prime a second line with NS and attach to the first IV line at the port closest to the patient (lowest port). Next, remove NS bag used to prime second line from the tubing, ensuring to maintain sterility and attach the tubing to the infusion bag.

8.7.4 PEDIATRIC UNIT PRIMING

8.7.4.1 If the IEC product is prepared in a syringe, it will be connected to a luer locking stopcock. The male end of the stopcock will be connected directly to the patient. The IEC product will then be administered via direct intravenous push with appropriate intravenous fluids provided at the bedside.

8.8 Do not use blood or filtered tubing.

8.9 The product will be released by the Stem Cell Transplant Laboratory personnel and transported as outlined by product dispensing guidelines.

8.10 The product will be accepted from the courier by the clinical team and/or nurse. Two licensed personnel will verify the product to be infused by double-checking the paperwork to the product.

8.11 Two licensed personnel will verify the IEC product to the patient’s armband at the bedside and confirm that the patient has received the prescribed pre-medications.

8.12 Vital signs will be monitored and documented at baseline, every 15 minutes until infusion is completed, and 30 minutes post infusion.

8.13 Begin IEC infusion.

8.13.1 If the patient has a reaction, the physician will be notified, and appropriate medical intervention will be taken. This may include slowing the infusion or stopping the infusion.

8.13.2 Reactions may include the following:

- Chills and fever
- Decrease in blood pressure
- Dizziness or light-headedness
- Shortness of breath or difficulty breathing
- Fast heart rate
- Nausea and vomiting
- Muscle and joint aches
- Headache
- Symptoms of Cytokine Release Syndrome
- Symptoms of Macrophage Activation Syndrome
- Symptoms of Tumor Lysis Syndrome
8.13.3 If the patient stabilizes, the product may be resumed at a slower rate after consultation with physician or designee.

8.14 The patient will be observed for a minimum of 1 hour following the infusion providing all vital signs are at baseline and patient is clinically stable. The patient will continue to be monitored to detect complications including signs of cytokine release syndrome and neurologic dysfunction for a minimum of the next 2 to 3 weeks. In the event of suspected cytokine release syndrome refer to APBMT-COMM-045 Management of Immune Effector Cell Therapy Complications for detailed management guidelines.

8.15 Should a deterioration in clinical status occur, there will be rapid escalation of care, increased intensity of monitoring, and relative workup to address complications and will include a written plan for communication of the transfer and ongoing management.

8.16 Communication to clinical staff, intensive care unit, emergency department, and pharmacy shall be comprehensive and timely, as applicable. (See Hospital Policies for Patient Transport).

8.17 Staff will document infusion on the SCTL-SOP-050 Infusion Form. Staff will also document the following into the electronic medical record:

8.17.1 Vital signs
8.17.2 Administration/Infusion times of all medications
8.17.3 Administration/Completion times of IEC infusion

8.18 Staff will document any adverse experiences on form STCL-GEN-050 Infusion Form.

8.19 Once the patient meets criteria for discharge to home, discharge instructions will be reviewed in detail with the patient, caregiver and/or or legally authorized representative as applicable.

8.20 Maintain documents per hospital policy.

9 RELATED DOCUMENTS/FORMS

9.1 APBMT-COMM-045 Management of Immune Effector Cell Therapy Complications
9.2 STCL-SOP-050 Infusion Form

10 REFERENCES

10.1 NA

11 REVISION HISTORY

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