

Cell Collection and Management Manual

Version 2
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Requirements for US Commercial Cilta-cel CAR-T Product

Cell Collection and Management Manual

This manual provides apheresis collection and management details for cilta-cel CAR-T product. Follow the apheresis eligibility requirements outlined below and patient eligibility according to institutional procedures and policies.

The responsible person at the site should notify the appropriate Janssen representative if evidence of (1) rapid disease progression or (2) suspected central nervous system involvement is observed between scheduling cell collection and the cell collection procedure.

Select the cryopreservation option prior to order submission. This will then ensure the proper shipper is sent to the site. Janssen will coordinate pick-up and delivery activities for patient material designated for an off-site (central) cryopreservation laboratory. Hospital sites qualified for local cryopreservation will manage their capacity within the cell processing laboratory. Janssen will coordinate pick-up of the cryopreserved apheresis material.

Apheresis collection bags should have 4 to 12 inches of tubing following collection to allow for future processing by welding onto this tubing.

Contents

Donor Eligibility for Cilta-cel CAR-T Product	4
Scheduling Apheresis Pick-up Time	4
Printing Labels	4
Cell Collection	4
Cell Management and Transport	5

Abbreviations

CAR-T	chimeric antigen receptor t cell
CoC	chain of custody
CoI	chain of identity
DIN/SEC-DIS	donation identification number/ single european code
ISBT	information standard for blood and transplant
WBC	white blood cells

Definition of Terms

Treatment Center Portal	A website-based order management platform to enable treatment site staff to enroll a patient, submit an order, and monitor the order journey for cilta-cel CAR-T product.
CoC/CoI Portal	The Chain of Custody (CoC)/ Chain of Identity (CoI) management portal used by the apheresis site staff for labelling and tracking a patient's order for cilta-cel CAR-T product.

Donor Eligibility for Cilta-cel CAR-T Product

1. Confirm appropriate Donor Infectious Disease testing was performed as per regional requirements.
2. Patient must meet the following criteria to be eligible for apheresis. Samples must be collected within 24 hours of apheresis;
 - Hemoglobin ≥ 8.0 grams/dL
 - Platelets $\geq 50 \times 10^9/L$
 - Absolute Lymphocyte Count $\geq 0.3 \times 10^9/L$
 - Absolute Neutrophil Count $\geq 0.75 \times 10^9/L$

Scheduling apheresis Pick-up Date

1. Use the Treatment Center Portal to schedule a pick-up date indicating the cryopreservation option. Once scheduled, Janssen will coordinate courier logistics.

Printing labels

1. Print the Packing Insert from the CoC/CoI Portal.
2. Print the cell collection bag labels from the hospital system following ISBT 128 (or equivalent) requirements. Perform label content verification as per site procedures.

Cell Collection

1. The use of Anticoagulant Citrate Dextrose solution, solution-A (ACD-A) or ACD-A plus heparin is permissible. Use of heparin alone is not permitted.
2. Affix the cell collection bag labels to the cell collection bag according to site procedures. Confirm patient identity against collection bag label prior to the start of collection.
3. Perform peripheral blood cell collection according to institutional procedures and policy for peripheral blood mononuclear cell collection.
4. Target a collection of $9.0 \pm 3.0 \times 10^9$ WBC. A minimum of $\geq 1.0 \times 10^9$ WBC is required.
5. Place the cells at 2°C to 8°C as soon as practical within 1 hour of apheresis.
6. Enter collection details including DIN, patient weight, and collection end time into the CoC/CoI Portal.



If $\geq 1.0 \times 10^9$ WBCs is not collected on the first apheresis attempt, communicate with Janssen Global Cell Collection.

Cell Management and Transport

1. If using off-site central cryopreservation, transfer the apheresis material to the appropriate location as per site procedure. See the *Packing and Shipment of Mononuclear Cell Apheresis Collection for Central Cryopreservation Manual* for further details.
2. If performing local cryopreservation, transfer the apheresis material to the cell processing laboratory according to site procedures. See the *Cell Cryopreservation Procedure Manual* for further details regarding cryopreservation.
3. Manage product tracing (CoC/CoI) for the apheresis material according to site procedures.

For questions related to the information in this manual, contact Janssen Global Cell Collection.