

# Cell Collection and Management Manual

Version 4

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Requirements for US Commercial CARVYKTI®

# Cell Collection and Management Manual

This manual provides apheresis collection and management details for CARVYKTI®. Follow the apheresis eligibility requirements outlined below and patient eligibility requirements according to treatment center's procedures and policies.

The responsible person at the treatment center should notify the appropriate Janssen representative if evidence of (1) rapid disease progression and/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: Central or Local Cryopreservation. This will then ensure the proper shipper is sent to the treatment center.

**1. Off-Site (Central) Cryopreservation:**

Janssen will coordinate pick-up and delivery activities for patient materials designated for an off-site (central) cryopreservation laboratory.

**2. Local Cryopreservation:**

Treatment centers qualified for local cryopreservation will manage their capacity within their designated cell processing laboratory. Janssen will coordinate pick-up of the cryopreserved apheresis material with the treatment center or designated cell processing laboratory.

## Contents

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Donation Eligibility for CARVYKTI®	4
Scheduling Apheresis Pick-up Date	4
Printing Labels	4
Cell Collection	5
Cell Management and Transport	5

## Abbreviations

CAR-T	Chimeric Antigen Receptor-T Cell
CoC	Chain of Custody
CoI	Chain of Identity
ISBT	Information Standard for Blood and Transplant
WBC	White Blood Cell

## Definition of Terms

Treatment Center Portal	A website-based order management platform to enable treatment center staff to enroll a patient, submit an order, and monitor the order journey for CARVYKTI®.
CoC/CoI Portal	The Chain of Custody (CoC)/Chain of Identity (CoI) management portal is used to track the handoffs throughout the CARVYKTI® order fulfillment process.

## Donation Eligibility for CARVYKTI®

1. Confirm appropriate Donor Infectious Disease testing was performed as per regional requirements.
2. It is recommended patients meet the following criteria to be eligible for apheresis.
  - Hemoglobin  $\geq$  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 logistics with a courier.

## Printing Labels

1. Print the Packing Insert from the CoC/CoI Portal.
2. Print the cell collection bag labels from the treatment center's system following ISBT 128 (or equivalent) requirements. Perform label content verification as per treatment center's 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 treatment center's procedures. Confirm patient identity against collection bag label prior to the start of collection.
3. Perform peripheral blood cell collection according to treatment center's procedures and policies for peripheral blood mononuclear cell collection.

*Note:* In lieu of the treatment center's specific procedures, the guidance below can be utilized to achieve the target cell count for CARVYKTI® collections performed on the Spectra Optia®.

- **Step 1:** Obtain patient WBC count within 24 hours prior to apheresis (cells/mL).
- **Step 2:** Use the guidance below to estimate how many liters of whole blood to process. If the patient's Pre-WBC count is  $> 12 \times 10^6$  WBC/mL, notify your Janssen Global Cell Collection representative prior to starting the apheresis collection.

<p><b>Patient Pre-WBC</b>  <math>&lt; 3 \times 10^6</math> WBC/mL:            follow treatment center SOP</p>	<p><b>Patient Pre-WBC</b>  <math>3 - 6 \times 10^6</math> WBC/mL:            process up to 15 L</p>	<p><b>Patient Pre-WBC</b>  <math>&gt; 6 \times 10^6</math> WBC/mL:            process up to 10 L</p>
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4. Target a collection of  $9.0 \pm 3.0 \times 10^9$  WBCs. A minimum of  $\geq 1.0 \times 10^9$  WBCs is required.
5. Apheresis collection bags should have 4 to 12 inches of tubing following collection to allow for future processing by welding onto this tubing.
6. Place the cells at 2 °C to 8 °C as soon as feasible within 1 hour of apheresis.
7. Enter collection details, including DIN, patient weight and collection end time into the CoC/CoI Portal.



**If  $\geq 1.0 \times 10^9$  WBCs are not collected on the first apheresis attempt, contact 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 treatment center's procedures. See the *Packing and Shipment of White Blood 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 treatment center's procedures. See the *Cell Cryopreservation Procedure Manual* for further details regarding local cryopreservation requirements.
3. Manage product tracing (CoC/CoI) for the apheresis material according to treatment center's procedures.

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