

# Amendment: Breyanzi (liso-cel) Collection Requirements Adult MNC Collection Procedure Clinical & Commercial - The Americas

## PURPOSE

The purpose of this document is to define the updated apheresis collection requirements for Breyanzi/liso-cel (lisocabtagene maraleucel, JCAR017, BMS-986387) in the Adult MNC Collection Procedure Clinical & Commercial - The Americas, DOC-701332.

This guidance supersedes all previously listed collection requirements for Breyanzi/liso-cel (lisocabtagene maraleucel, liso-cel/JCAR017, BMS-986387) as detailed in Section 2.2 Collection Procedure, Table 3 – Collection Requirements of DOC-701332.

## A. SCOPE

This amendment is to be used with the Adult MNC Collection Procedure Clinical & Commercial - The Americas (DOC-701332) Section 2.2 Collection Procedure, Table 3 – Collection Requirements.

DOC-701332 outlines all other collection requirements for BMS cellular therapies and must be referenced for additional procedural details.

## B. COLLECTION REQUIREMENTS

1. Determine Whole Blood Process Volume Target (WBPV) using one of the following laboratory test results:
  - 1.1. Absolute Lymphocyte Count (ALC), refer to section 2.1.
  - 1.2. CD4+ and CD8+ flow cytometry, refer to section 2.2.
    - 1.2.1. CD4+ and CD8+ results performed on patient's blood prior to the collection, following institution policy.
    - 1.2.2. Recommended for patients with  $ALC \leq 0.4 \times 10.0^9/L$  or  $\geq 10.0^9/L$ .
    - 1.2.3. May be applied to all patients per apheresis site practice.
2. Collection Targets
  - 2.1. WBPV determined by ALC.
    - 2.1.1. Refer to patient's ALC results drawn within 24 hours of collection start to calculate collection targets. Refer to **Table 1** for collection targets.
      - 2.1.1.1.1. If ALC results are unable to be drawn within 24 hours prior to the start of the collection, contact Scheduling and Cell Logistics.
      - 2.1.1.1.2. The collection may be initiated prior to receipt of the ALC result.
        - Program the collection device to process highest WBPV.
        - Adjust the run target when ALC results are received, if required.
        - Contact Scheduling and Cell Logistics if the ALC is not received in time to adjust the targets.

**Note:** WBPV is a medical decision focused on patient safety. If the WBPV target cannot be reached, record a comment in the comments section of the Cell Therapy 360 Apheresis Portal.

**Table 1- WBPV determined by ALC**

ALC (Absolute Lymphocyte Count) x10 <sup>9</sup> /L						
ALC	<0.4	≥0.4 - <1.0	≥1.0 - <10.0	≥10.0	Autologous Plasma Volume Target	Total Product Volume
WBPV Target	17L	12L	7L	17L	150mL	≤ 540mL*

2.2. WBPV determined by CD4+ and CD8+ Target Cell Count in product.

2.2.1. Calculate the WBPV required to reach the Target Cell Count in product using institutional calculation, prior to the collection start.

2.2.1.1. Use the patient's CD4+ and CD8+ flow cytometry results obtained prior to the collection to perform the calculation used by the institution.

2.2.1.2. Refer to **Table 2** for CD4+ and CD8+ cell targets in the product.

2.2.1.2.1. The calculation to determine WBPV target should be performed using the lower value between the patient's circulating CD4+ or CD8+ cell counts.

2.2.1.2.2. The Minimum Target Cell Count in product may be used to determine the WBPV, if the higher Target Cell Count cannot be achieved. Refer to **Table 2**.

2.2.1.2.3. Contact Scheduling and Cell Logistics if the WBPV estimated to reach the Minimum Target Cell Count cannot be achieved.

2.2.2. Document the patient's CD4+ and CD8+ count used for calculation in the comments section of the Cell Therapy 360 Apheresis Portal.

2.2.3. Post-collection sampling the MNC product is not required by BMS. If institutional procedures require sampling refer to Adult MNC Collection Procedure Clinical & Commercial - The Americas Section 2.2, 2.2.18 for guidance.

2.2.3.1. Do not provide product sample test results to BMS, unless requested by BMS.

2.2.3.2. Do not delay packaging and shipping the MNC product to BMS while awaiting product sampling results.

**Table 2 - CD4+ and CD8+ Cell Collection Target in Product**

	CD4+ cell target	CD8+cell target	Autologous Plasma Volume Target	Total Product Volume
Target Cell Count in product	700 x10E6	700 x10E6	150mL	≤ 540mL*
Minimum Target Cell count in product	370 x10E6	370 x10E6	150mL	≤ 540mL*

\* **Note:** Contact Scheduling and Cell Logistics if the Total Product Volume is expected to be >540mL.

### C. REFERENCES

- DOC-701332: Adult MNC Collection Procedure Clinical & Commercial - The Americas

### D. DOCUMENT HISTORY

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See BMSDocs Overlay	2.0	Suzanne Montag
<b>Description of Change &amp; Change Justification</b>		
<ul style="list-style-type: none"><li>• Corrected ALC values in Table 1</li><li>• Revised document title</li></ul>		
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Effective Date	Version Number	Author(s)
09DEC2025	1.0	Suzanne Montag
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