

4006: Cellular Therapy Infusion

This form must be completed for all infusions for recipients of non-HCT cellular therapy (including post-HCT “DCI / DLI” infusions). For recipients of hematopoietic cellular transplants (HCT), complete the Hematopoietic Stem Cell Transplant (HCT) Infusion (2006) form.

The Cellular Therapy Infusion (4006) form is designed to capture infusion-specific information for all infusions given to a recipient as part of a course of cellular therapy. In addition to use in research, this information is used for quality assurance measures, both by the NMDP and the Cord Blood Banks.

Product specific information is collected on Cellular Therapy Product (4003) form. A Cellular Therapy Product (4003) form is required for each product and a Cellular Therapy Infusion (4006) form is required for each infusion of that product. For example, a single product may be infused three times per course of cellular therapy. In this scenario, one Cellular Therapy Product (4003) form and three Cellular Therapy Infusion (4006) forms would be completed.

If more than one infusion occurs, as defined by event date, each infusion must be analyzed and reported on a separate Cellular Therapy Product (4006) form. This is true even if the same product is being infused on a later date.

For more information see [Appendix D–How to Distinguish Infusion Types](#) and [Appendix E–Definition of a Product](#).

Links to sections of form:

[Q1-31: Product Infusion](#)

[Q32-35: Concomitant Therapy](#)

Date	Manual Section	Add/Remove/Modify	Description
1/22/2021	4006: Cellular Therapy Infusion	Modify	Version 5 of the 4006: Cellular Therapy Infusion section of the Forms Instruction Manual released. Version 5 corresponds to revision 5 of the Form 4006.

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Q1-31: Product Identification

Question 1: Name of product:

- * If your center considers this to be a Donor Lymphocyte Infusions (DLI), as reported on the Pre-CTED (4000) form, product name will not be auto-populated. Select **Other product** for the product name.

The name of the product reported will be auto populated from what was reported on Pre-Cellular Therapy Essential Data (4000) form. This question is limited to commercially available or pre-commercial products and is used to disable questions related to manufacturing.

If a commercially available product is selected, several questions on this form will be disabled and cannot be answered.

- * Questions 2-5: Not all identifiers below are applicable to all products. The ID / number should be found with the product bag or shipping manifest. Choose the identifier that is most appropriate. Please do not override a field, but rather select **Yes** or **No**.

Question 2-5: Specify the identifiers associated with this cell product (check all that apply)

Cell product ID: Product IDs can be numeric or alphanumeric.

- * If the cellular therapy product infused is the commercially available product Breyanzi™, the JOIN ID must be reported in the Cell product ID field and is available on the Release For Infusion (RFI).

- * If the cellular therapy product infused is the commercially available product Kymriah®, the product code(s) can be reported in the Cell product ID field and is available on the Certificate of Analysis (COA) or Dose Report.

If the cell product has a cell product ID, specify the ID in question 3. Product IDs can be numeric or alphanumeric.

Batch number: Batch numbers can be numeric or alphanumeric.

- * If the cellular therapy product infused is the commercially available product Kymriah®, the batch number must be reported and is available with the information that comes with the

product.

- * If the cellular therapy product infused is the commercially available product Yescarta®, do not report a batch number.

Lot number: Lot numbers can be numeric or alphanumeric.

- * If the cellular therapy product infused is the commercially available product Yescarta® or Tecartus®, the lot number must be reported and is available with the information that comes with the product.

- * If the cellular therapy product infused is the commercially available product Kymriah®, do not report a lot number.

- * If the cellular therapy product infused is the commercially available product Breyanzi™, report the lot numbers for both the CD4+ and CD8+ components in the same field (separate values by a comma).

Question 6: Date of this product infusion:

Report the date (YYYY-MM-DD) this product was infused. If the product was infused over multiple days, report the start date of infusion.

If the exact date is unknown, please view [General Instructions, General Guidelines for Completing Forms](#) for more information on reporting partial and unknown dates.

Question 7-9: Was the entire volume of product infused?

If the product being infused as a cellular therapy is a portion from a prior HCT (e.g., DLI / DCI), the portion becomes the “entire” product for the purposes of this form. The intent is to capture if the product being infused was given in its entirety or not. If the entire volume of the product was not infused, select **No** and specify what happened to the reserved portion in questions 8 – 9.

If multiple bags of a commercially available product are shipped to your center and one or more bags are stored for future infusions, report **No** and specify what happened to the reserved portion in questions 8 – 9.

Questions 10-13: Specify the route of product infusion:

- * If the cellular therapy product infused is the commercially available product Kymriah®, Yescarta®, or Tecartus™ report the route of infusion as Intravenous.

Specify the route of product infusion.

- **Intravenous** refers to an infusion into the veins – examples include infusion via central line or via catheter.
- **Intramedullary** refers to an infusion into the marrow cavity within a bone, such as directly into the proximal tibia or anterior aspect of the femur.
- **Intraperitoneal** refers to an infusion within the peritoneal cavity.
- **Intra arterial** refers to an infusion within an artery or arteries.
- **Intramuscular** refers to an infusion within a muscle.
- **Intrathecal** refers to an infusion within the cerebrospinal fluid at any level of the cerebrospinal axis, including injection into the cerebral ventricles.
- **Intraorgan** refers to an infusion within an organ such as the heart, liver, lungs, etc. If the route or product infusion is **Intraorgan**, indicate the site in question 12. If **Other site** is selected, specify the other site in question 13.
- **Locally in the tissue** refers to an infusion in a restricted area of the body or in a tumor that cannot be classified as intraorgan, includes subcutaneous.

If the route of infusion is not one of the above options, select **Other route of infusion** and specify the infusion route in question 11.

**Question 14-31: Reporting total number of cells**

Report the total number of cells (not cells per kilogram) contained in the product administered.

This section collects the total number of cells that were infused in a specific product. All of the cells listed on the Cellular Therapy Product (4003) form (question 6) should be included here. Only report the cells that are applicable to this infusion. Note, CD3 is present on all T-cells whether they are CD4+ or CD8+ T- cells.

- * Cell counts are not released for the commercially available product Yescarta® or Tecartus®. The following questions will be disabled and cannot be answered.

- * Product specific reporting guides for reporting cells administered can be requested for Kymriah® and Breyanzi™ by contacting CIBMTR Center Support.

Question 14-15: Total number of cells administered:

Report the total cell count contained in the product administered. If the type of cells is not specified, report the total number of cells present at time of the infusion. If multiple bags were infused together, report the sum of each bag.

Question 16-31: Specify the cell type(s) administered (check all that apply)

If the cellular therapy product infused is the commercially available product Kymriah®, you can contact CIBMTR Center Support and request the Reporting Guide.

Lymphocytes (unselected): Unselected means a specific lymphocyte sub-population (e.g. CD4+) was not targeted. This includes all types of lymphocytes, those that have not been selected via flow cytometry or other method. Report the total number of unselected lymphocytes (e.g., CD3+ cells) administered in the product in question 17.

CD4+ lymphocytes: The lab report may display this value as CD3+CD4+. These cells are also known as T-helper cells. Report the total number of CD4+ cells administered in the product in question 18.

CD8+ lymphocytes: The lab report may display this value as CD3+CD8+. These cells are also known as cytotoxic T-cells which can destroy virus-infected cells, tumor cells, tissue grafts, etc. Report the total number of CD8+ cells administered in the product in question 19.

Regulatory T-cells (TREG): TREG cells express the biomarkers CD4, FOXP3, and CD25. Report the total number of TREG cells administered in the product in question 20.

Cardiac progenitor cells: Cardiac progenitor cells are tissue-specific stem progenitor cells within the heart. Report the total number of cardiac progenitor cells administered in the product in question 21.

Dendritic cells / tumor cell hybridomas (tumor vaccines): Dendritic cells are antigen-presenting cells (also known as accessory cells) of the immune system. Their main function is to process antigen material and present it on the cell surface to the T-cells of the immune system. Report the total number of dendritic cells or tumor cell hybridomas administered in the product in question 22.

Endothelial progenitor cells (EPC): EPC is a term that is applied to multiple different cell types that play roles in the regeneration of the endothelial lining of blood vessels. Report the total number of endothelial progenitor cells (EPCs) in the product in question 23.

Human umbilical cord perivascular (HUCPV) cells: HUCPV cell is a term that is applied to mesenchymal, non-hematopoietic, non-endothelial cells that are isolated from the umbilical cord. Report the total number of human umbilical cord perivascular (HUCPV) cells in the product in question 24.

Islet cells: Islet cells are found in the pancreas. The pancreas contains clusters of cells that produce hormones and these clusters are known as islets. Report the total number of islet cells administered in the product in question 25.

Mesenchymal stromal stem cells (MSCs): MSCs are multipotent stromal cells that can differentiate into a variety of cell types, including osteoblasts (bone cells), chondrocytes (cartilage cells), myocytes (muscle cells) and adipocytes (fat cells). Report the total number of MSCs administered in the product in question 26.

Natural killer cells (NK cells): NK cells are a type of cytotoxic lymphocyte critical to the innate immune system. They usually express CD56 / CD16 on their cell surface. Report the total number of natural killer cells (NK cells) administered in the product in question 27.

Oligodendrocytes: Oligodendrocytes are glial cells similar to an astrocyte but with fewer protuberances. These cells produce myelin in the central nervous system. Report the total number of oligodendrocytes administered in the product in question 28.

Unspecified mononuclear cells: A mononuclear cell is defined as any blood cell with a round nucleus (i.e., a lymphocyte, a monocyte, or a macrophage). These blood cells are a critical component of the immune system's ability to fight infection and adapt to intruders. Report the total number of unspecified mononuclear cells administered in the product in question 29.

Other cell type: If a different cell type not previously mentioned was infused, specify the other cell type in question 30 and report the total number administered in the infusion in question 31.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
1	7/20/2021	Add	Added blue note box for product name: For DCI/DLIs, product name will not be auto-populated. Select "Other product" for the product name.	Clarification on reporting a product name for DCI/DLIs
2	7/21/2021	Modify	Clarified where to find the JOIN ID for Breyanzi™ products	
2	7/21/2021	Modify	Added "Tecartus®" to blue note box below lot number	Lot number is required for Tecartus™ products
2	7/21/2021	Add	Added blue note box on reporting Lot number for Breyanzi™ products	This is a new product and instruction did not exist previously

14	7/21/2021	Add	Added blue note box above question 14: %(color-red)Product specific reporting guides for reporting cells administered can be requested for Kymriah® and Breyanzi™ by contacting CIBMTR Center Support. %	New instruction
14	7/21/2021	Modify	Added “Tecartus®” to blue note box above question 14: Cell counts are not released for the commercially available product Yescarta® or Tecartus™. The following questions will be disabled and cannot be answered.	Cell counts are not released for Tecartus™ products

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Q32-35: Concomitant Therapy

Question 32: Did the recipient receive concomitant therapy?

Concomitant therapy is given to enhance the function of the cellular therapy. In cases where a recipient has both HCT and cell therapy, this question applies to the cell therapy infusion, not the HCT. If the recipient had a prior HCT and the therapy was already captured on the HCT form as being HCT prep regimen, it is not reported again. See question 33 for a list of drugs that can be given as concomitant therapy.



Questions 33-35 Reporting More Than One Concomitant Therapy

FormsNet3SM application: Complete questions 33-35 for each concomitant therapy by adding an additional instance in the FormsNetSM application.

Paper form submission: Copy questions 33-35 and complete for each concomitant therapy.

Question 33-34: Specify drugs:

Select the drug(s) given as concomitant therapy. If the drug given is not in the list, check **Other** and specify the drug in question 34.

Question 35: Specify time point:

Concomitant therapy can be given simultaneously with the cellular therapy infusion or up to 24 hours after infusion (post cell therapy).

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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