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
10/ 27/ 2022	Q1-31: Product Identification	Modify	Added Carvykti™ to the blue note box above below14: If the cellular therapy product infused is the commercially available product Kymriah® ,or BreyanziTM, Abecma®, or Carvykti™ this question will be disabled.
9/29/ 2021	Q1-31: Product Identification	Modify	Added Carvykti™ to the blue note box above question 14: Product specific reporting guides for reporting cells administered can be requested for Kymriah®, Breyanzi™, Abecma®, and Carvykti™ by contacting CIBMTR Center Support.
9/23/ 2022	4006: Cellular Therapy Infusion	Modify	Updated for new DLI reporting process: This form must be completed for all products 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.

			For recipients of Donor Lymphocyte Infusions (DLI), complete the Donor Lymphocyte Infusion (2199) form.
9/23/2022	4006: Cellular Therapy Infusion	Remove	Removed blue note box below question 1: ~~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~~
9/23/2022	4006: Cellular Therapy Infusion	Modify	Added commercially available CAR-T product Carvykti™ to the blue note box below Batch number in question 2-5: If the cellular therapy product infused is the commercially available product Kymriah® or Carvykti™, the batch number must be reported and is available with the information that comes with the product.
9/23/2022	4006: Cellular Therapy Infusion	Modify	Removed the reference to DLI: 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.
9/23/2022	4006: Cellular Therapy Infusion	Modify	Added commercially available CAR-T product Carvykti™ to the blue note box below question 10-13: If the cellular therapy product infused is the commercially available product Kymriah®, Yescarta®, Tecartus™, BreyanziTM, or Abecma®, or Carvykti™ report the route of infusion as Intravenous.
5/10/2022	4006: Cellular Therapy Infusion	Modify	Removed Breyanzi from the blue note box below question 14: If the cellular therapy product infused is the commercially available product Kymriah® ~~,~~ ~~BreyanziTM,~~ or Abemca®, this question will be disabled.
1/28/2022	4006: Cellular Therapy Infusion	Modify	Version 6 of the 4006: Cellular Therapy Infusion section of the Forms Instruction Manual released. Version 6 corresponds to revision 6 of the Form 4006.

Last modified: Oct 27, 2022

Q1-31: Product Identification

Question 1: Name of product:

The name of the product reported will be auto populated from what was reported on Pre-Cellular Therapy Essential Data (4000) form. If the cellular therapy product infused is a commercially available or pre-commercial product, this question is used to disable questions related to manufacturing.

> ✻ 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.

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™ or Abecma®, 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.

Batch number: Batch numbers can be numeric or alphanumeric.

> ✻ If the cellular therapy product infused is the commercially available product Kymriah® or Carvykti™, 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® or Tecartus®, do not report a batch number.

If the cell product has a batch number, specify the batch number in question 4.

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).

If the cell product has a lot number, specify the lot number in question 5.

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 first 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., 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®, Tecartus™, Breyanzi™, Abecma®, or Carvykti™ 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®, Breyanzi™, Abecma®, and Carvykti™ by contacting CIBMTR Center Support.

Question 14-15: Total number of cells administered:

If the cellular therapy product infused is the commercially available product Kymriah®, Abecma®, or Carvykti™, this question will be disabled.

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)

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)
14	10/27/ 2022	Modify	Added Carvykti™ to the blue note box above below14: If the cellular therapy product infused is the commercially available product Kymriah® ,or BreyanziTM, Abecma®, or Carvykti™ this question will be disabled.	The validation was updated to disable this question for Carvykti™
14	9/29/ 2022	Modify	Added Carvykti™ to the blue note box above question 14: Product specific reporting guides for reporting cells administered can be requested for Kymriah®, Breyanzi™, Abecma®, and Carvykti™ by contacting CIBMTR Center Support.	The Carvykti™ reporting guide is now available
1	7/29/ 2021	Remove	Removed blue note box below question 1: ~~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~~	DLIs are no longer reported on the F4006.
2-5	7/29/ 2022	Modify	Added commercially available CAR-T product Carvykti™ to the blue note box below Batch number in question 2-5: If the cellular therapy product infused is the commercially available product Kymriah® or Carvykti™, the batch number must be reported and is available with the information that comes with the product.	Carvykti™ was approved for commercial infusion in Feb 2022.
7-9	7/29/ 2022	Modify	Removed the reference to DLI: If the product being infused as a cellular therapy is a portion from a prior HCT (e.g.,	DLIs are no longer reported

			-%(color-red)DLI / %-DCI), the portion becomes the “entire” product for the purposes of this form.	on the F4006
10-13	7/29/ 2022	Modify	Added commercially available CAR-T product Carvykti™ to the blue note box below question 10-13: If the cellular therapy product infused is the commercially available product Kymriah®, Yescarta®, Tecartus™, BreyanziTM, or Abecma®, or Carvykti™ report the route of infusion as Intravenous.	Carvykti™ was approved for commercial infusion in Feb 2022.
14	5/10/ 2022	Modify	Removed Breyanzi from the blue note box below question 14: If the cellular therapy product infused is the commercially available product Kymriah® ~~, BreyanziTM,~~ or Abemca®, this question will be disabled.	This question should be answered for the commercially available product Breyanzi™

Last modified: Oct 27, 2022

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 34 for a list of drugs that can be given as concomitant therapy.

> ✻ Questions 33-35 Reporting More Than One Concomitant Therapy
> FormsNet3^{SM} application: Complete questions 33-35 for each concomitant therapy by adding an additional instance in the FormsNet^{SM} application.
> Paper form submission: Copy questions 33-35 and complete for each concomitant therapy.

Question 33: Specify start date:

Report the start date of the drug selected in question 342. Concomitant therapy can be given simultaneously with the cellular therapy infusion or up to 24 hours after infusion (post cell therapy).

Question 34-35: 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 35.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Sep 23, 2022