# 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 appropriate HCT infusion form (Form 2006).

The Form 4006 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 Form 4003. A Form 4003 is required for each product and a Form 4006 is required for each infusion of that product. For example, a single product may be infused three times per course of cellular therapy.

If more than one infusion occurs, as defined by event date, each infusion must be analyzed and reported on a separate form 4006. This is true even if it's the same product 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:
Q1-45: Product Infusion
Q46-49: Concomitant Therapy

| Date | Manual Section | Add/ Remove/ Modify | Description |
|---|---|---|---|
| 8/29/ 2019 | "4006: Product Identification" | Modify | Updated instruction in pink warning box above question 17: **Question 17-45: Reporting total number of cells**<br>Report the total number of cells (not cells per kilogram) contained in the product administered ~~not corrected for viability~~. |
| 6/27/ 19 | 4006: Cellular Therapy Infusion | Modify | Added additional information to the manual providing specific reporting instructions for commercially available products. |
| 4/10/ 18 | 4006: Cellular Therapy Infusion | Add | Added in additional clarification regarding total cell counts administered, what constitutes unselected lymphocytes, and T-helper cells (Q17-24). |
| 3/8/ 18 | 4006: Cellular Therapy | Add | Added **Product Identification** note box above question 1. |

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|---|---|---|---|
| | Infusion | | |
| 1/30/18 | 4006: Cellular Therapy Infusion | Modify | Version 3 of the 4006: Cell Therapy Infusion section of the Forms Instructions Manual released. Version 3 corresponds to revision 3 of the Form 4006. |

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# Q1-45: Product Identification

Questions 1-6: Not all of these identifiers 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 1-2: Cell product ID :

If the cellular therapy product infused is the commercially available product Kymriah® or Yescarta®, report the cell product ID as “no”.

Report if the product has a Cell product ID in question 1 and specify the ID in question 2. Product IDs can be numeric or alphanumeric.

### Question 3-4: Batch number:

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®, report the batch number as “no”.

Report if the product has a Batch number in question 3 and specify the Batch number in question 4. Batch numbers can be numeric or alphanumeric

### Question 5-6: Lot number:

If the cellular therapy product infused is the commercially available product Kymriah®, report the lot number as “no”.

If the cellular therapy product infused is the commercially available product Yescarta®, the

> lot number must be reported and is available with the information that comes with the product.

Report if the product has a Lot number in question 5 and specify the Lot number in question 6. Lot numbers can be numeric or alphanumeric

### Question 7: 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 8-10: Was the entire volume of product infused?

If the product being infused as a cellular therapy (e.g. DLI/DCI) is a portion from a prior HCT, 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, specify what happened to the reserved portion in question 9 and 10.

### Question 11-12: Specify the route of product infusion:

> ✻ If the cellular therapy product infused is the commercially available product Kymriah® or Yescarta®, report the route of infusion as “intravenous”.

Report the route by which the product was infused.

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. Specify the 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.

If the route of infusion is not one of the above options, select “other route of infusion” and specify the infusion route in question 12.

### Question 13-14: Specify the site of intraorgan administration of cells:

If the route of product infusion was intraorgan, specify the site of intraorgan administration. If the site of infusion is not in the option list, select “other site” and specify the site in question 14.

### Question 15: Recipient weight used for this infusion:

Report the recipient’s actual body weight used to calculate the cell dose for this infusion. This weight is usually documented on infusion orders or admitting orders. Report weight to the nearest whole kilogram or pound (round up if 0.5 or greater). Do not report adjusted body weight, lean body weight, or ideal body weight.

### Question 16: Recipient height used for this infusion:

Report the recipient’s height at infusion. Report the recipient’s height to the nearest whole centimeter or inch (round up if 0.5 or greater).

> **Question 17-45: 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 that were listed on the F4000 Pre-CTED in question 36 are included here. Only respond to 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®. Report “unknown” or “no” for all cell types listed in questions 17-45.

### Question 17-18: Total number of cells administered:

Report the total cell count contained in the product administered, not corrected for viability. If the type of

cells are 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 19-20: Lymphocytes (unselected) administered:

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. If yes, report the total number of unselected lymphocytes (e.g., CD3+ cells) administered in the product in question 20.

### Question 21-22: CD4+ lymphocytes administered:

The lab report may display this value as CD3+CD4+. These cells are also known as T-helper cells. If yes, report the total number of CD4+ cells administered in the product in question 22.

### Question 23-24: CD8+ lymphocytes administered:

The lab report may display this value as CD3+CD8+. These cells are also known as T-helper cells. If yes, report the total number of CD8+ cells administered in the product in question 24.

### Question 25-26: Natural killer cells (NK cells) administered:

NK cells are a type of cytotoxic lymphocyte critical to the innate immune system. They usually express CD56 / CD16 on their cell surface. If yes, report the total number of natural killer cells (NK cells) administered in the product in question 26.

### Question 27-28: Dendritic cells / tumor cell hybridomas administered:

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. If yes, report the total number of dendritic cells or tumor cell hybridomas administered in the product in question 28.

### Question 29-30: Mesenchymal stromal stem cells (MSCs) administered:

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). If yes, report the total number of MSCs administered in the product in question 30.

### Question 31-32: Unspecified mononuclear cells administered:

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. If yes, report the total number of unspecified mononuclear cells administered in the product in question 32.

### Question 33-34: Endothelial progenitor cells (EPC) administered:

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. If yes, report the total number of endothelial progenitor cells (EPCs) in the product in question 34.

### Question 35-36: Human umbilical cord perivascular (HUCPV) cells administered:

HUCPV cell is a term that is applied to mesenchymal, non-hematopoietic, non-endothelial cells that are isolated from the umbilical cord. If yes, report the total number of human umbilical cord perivascular (HUCPV) cells in the product in question 36

### Question 37-38: Cardiac progenitor cells administered:

Cardiac progenitor cells are tissue-specific stem progenitor cells within the heart. If yes, report the total number of cardiac progenitor cells administered in the product in question 38.

### Question 39-40: Islet cells administered:

Islet cells are found in the pancreas. The pancreas contains clusters of cells that produce hormones and these clusters are known as islets. If yes, report the total number of islet cells administered in the product in question 40.

### Question 41-42: Oligodendrocytes administered:

Oligodendrocytes are glial cells similar to an astrocyte but with fewer protuberances. These cells produce myelin in the central nervous system. If yes, report the total number of oligodendrocytes administered in the product in question 42.

### Question 43–45: Other cell type administered:

If a different cell type not previously mentioned was infused, specify the other cell type in question 44 and report the total number administered in the infusion in question 45.

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# Q46-49: Concomitant Therapy

### Question 46: Did the recipient receive concomitant therapy?

Concomitant therapy is therapy 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 47 for a list of drugs that can be given as concomitant therapy.

### Question 47-48: Specify drugs: (check all that apply)

Select the drug(s) given as concomitant therapy. If the drug given is not in the list, check “other” and specify the other drug in question 48.

### Question 49: Specify time point:

This question applies to the therapy as a whole, not to each individual drug. Concomitant therapy can be given simultaneously with the cellular therapy infusion or up to 24 hours after infusion (post cell therapy).

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