How to Distinguish Infusion Types

This appendix includes definitions of *Hematopoietic Stem Cell Transplant (HSCT), Donor Cellular Infusion (DCI), Supplemental Infusion, and Autologous Cells Given for Graft Failure.* For more information see Table 1 on page 3 of this document.

Hematopoietic Stem Cell Transplant (HSCT) – Primary or Subsequent

An HSCT is an infusion of a product (i.e. bone marrow, PBSC, cord blood, etc.) that contains CD34+ cells. The intention of an HSCT is to restore hematopoiesis and immunity and is usually preceded by a preparative regimen which is used to kill normal cells, cancer cells (if present), and to prevent rejection. However, a preparative regimen may not be used prior to a stem cell "boost" or for diseases such as immune deficiencies, although these indications are still considered an HSCT.

Donor Cellular Infusion (DCI)

A DCI is a form of immunotherapy that is commonly used to treat infections (e.g. viral) or recurrent disease. A DCI may also be utilized to treat GVHD or promote engraftment when chimerism studies reveal less than 100% donor cells. The recipient does not receive a preparative regimen prior to receiving the additional donor cells.

A DCI should not be reported if additional donor cells are given for failed ANC recovery, partial or poor ANC recovery, loss of graft, or late graft failure. This, instead, would be considered a subsequent HSCT.

The types of cells used for a DCI include, but are not limited to the following:

- Lymphocytes (TC- T Cells: A therapeutic product from any source containing a quantified T-cell population.)
- Peripheral blood mononuclear cells (both stimulated and unstimulated) (TC, Whole Blood: Whole blood collected as a source of nucleated cells intended for therapeutic use other than HPCs.)
- Dendritic cells from the original donor (TC- DC: A therapeutic cell product containing dendritic cells for therapeutic use.)
- Mesenchymal cells (TC- MSC: A therapeutic product containing mesenchymal stromal cells for therapeutic use.)

Supplemental Infusion

A supplemental infusion is defined as an infusion of cells given prior to clinical day 0 (of an HSCT) for any reason other than to produce engraftment. An infusion of supplemental cells is often given in conjunction with a preparative regimen for an HSCT. A Supplemental infusion is distinct from a DCI as it is given prior to an HSCT, whereas a DCI is given after an HSCT.

Examples of supplemental infusions include, but are not limited to the following:

- NK Cells
- T-Regulatory cells
- Mesenchymal cells

Supplemental infusion cells should be reported in the "**Cell Source**" section of the Pre-TED, in the "Other" and "Specify cell source" fields. The cell source that is intended to produce engraftment should also be reported in the "**Cell Source**" section of the Pre-TED.

When reporting supplemental infusions, an additional INF Form may be required for some TED Forms and all Comprehensive Report Forms. This information is reported on the INF Form because of the timeframe in which these cells are administered, prior to transplant.

Autologous Cells given for graft failure

Following an HSCT, a recipient may receive an infusion of autologous cells as a result of poor hematopoietic recovery or graft failure/rejection. The CIBMTR defines this type of infusion as a *subsequent HSCT*; however, because the research value of these data does not justify the additional reporting burden to transplant centers, the CIBMTR does not currently require additional forms in the event of these transplants. The data is reported on the Follow-up Forms.

Table 1. Distinguishing Infusion Types

	HSCT (primary or subsequent)	DCI (post-HSCT)	Supplemental cells infusion	Autologous cells given for graft failure
Purpose of infusion:	Replace or repopulate recipient marrow and reconstitute immune system.	Used to treat infections (e.g. viral) or recurrent disease by creating an immune effect within the recipient.	Supplemental cells have multiple purposes including 1) anti-tumor effect (i.e. NK cells) or 2) immune modulatory effect (i.e. T-cells).	Replace or repopulate recipient marrow and reconstitute immune system. Usually, this procedure is used until the next course of action is determined.
Composition of infusion:	Must contain HPCs (hematopoietic progenitor cells). They are also referred to as CD34+ cells or stem cells.	The cells of action are not stem cells, but the infusion may contain stem cells. Examples include, but are not limited to: lymphocytes, peripheral blood mononuclear cells (both stimulated and unstimulated), dendritic cells from the original donor, and mesenchymal cells.	The cells of action are not stem cells, but the infusion may contain stem cells. Examples include NK Cells, T-Regulatory cells, and mesenchymal cells. Cord blood may also be utilized for supplemental cell infusions.	Must contain HPCs (hematopoietic progenitor cells). They are also referred to as CD34+ cells or stem cells.
Preparative regimen:	A preparative regimen is typically used. Exceptions include, but are not limited to: • Recipient's disease does not require preparative regimen (e.g., SCID, WAS, etc.) • Subsequent HSCT for no ANC recovery, partial or poor ANC recovery, loss of graft, or late graft failure.	A preparative regimen is not used. However, therapy may be given to treat the recipient's disease between the HSCT and first DCI, or between DCIs. Examples of therapy include, but are not limited to: Rituximab, CHOP, 7 + 3, mylotarg, and steroids.	These cells are typically given during the preparative regimen for an HSCT.	A preparative regimen is not used.
CIBMTR form where data is reported:	INF Form 2006	Post-TED or Comprehensive Report Form (2100, 2200 and/or 2300) depending on track selected by algorithm.	INF Form 2006	No additional forms. Continue reporting on first transplant Post-TED or Comprehensive Report Form (2100, 2200 and/or 2300) depending on track selected by algorithm.