CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

February/March 2019 Forms Instruction Manual Updates

In case you missed them, here are the changes made to the Forms Instruction Manual during the months of February and March. Check the "Getting Started" page of the Forms Instruction Manual for a list of the most recent updates. Updates made after March 2015 are always available for reference in the "Historical Manual Updates" section.

Date	Manual Section	Add/ Remove/ Modify	Description
2/1/19	Cellular Therapy Manuals	Modify	Added clarification (in red below): *What cellular therapies to report and when:* 1. *Cellular therapy given in context of HCT (e.g. co-infusion, DLI/DCI): When a cellular therapy is given in context of a transplant, such as a co-infusion with an HCT or a DLI/DCI post-HCT, these infusions need to be reported to the CIBMTR. This includes both autologous and allogeneic products, such as cell stored prior to an allogeneic HCT used for treatment of graft failure.* 2. *Cellular therapy given with a prior HCT (e.g. CAR T-cell therapy for treatment of relapse): When a cellular therapy (e.g. CAR T-cell therapy) is given and there is a prior HCT, reporting these infusions are voluntary at this time.* 3. *Stand-alone cellular therapy (no prior HCT) (e.g. CAR T-cells): reporting these infusions are voluntary at this time*.* **Reporting of commercial products infusions (i.e. Kymriah, Yescarta) is strongly encouraged.*
2/27/19	2556: Myelofibrosis Pre-HCT Data and 2557: Myelofibrosis Post-HCT Data	Remove	Removed text referencing the CMS study for Myelofibrosis. The 2556 and 2557 are required for all patients with Myelofibrosis, not just patients enrolled in the CMS study. The titles of the forms have already been changed to remove CMS study from the title.
2/27/19	2400: Pre-TED	Modify	Modified (removed text is struck out below, updated text is in red) the instructions for question 52 on where to report cellular therapy product data for products that are not intended to achieve hematopoietic engraftment. *If infusions of additional cells (not intended to produce engraftment) were given prior to the HCT being reported (i.e., prior to clinical day 0), the cells must be reported as a product on the Pre-TED Form (Form 2400, question 51) and on a separate Cellular Therapy ~~Infusion~~ Product Form (Form ~~4006~~ 4003). If the additional cells were infused post-HCT, for any reason other than a subsequent HCT, they should be reported as a DCI on the appropriate follow-up form. Reporting the additional cells (given pre-HCT and not intended to produce engraftment) on the Form ~~4006~~ 4003 is the only mechanism the CIBMTR has in place to collect this data and ensure that the quality assurance data is reported to cord blood banks, if applicable.*
	2006:		Added additional instruction (in red below) regarding T-Cell depletion under questions 73-95:

2/27/19	2000: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	***T-Cell depletion**: T-cell depletion removes some or all of the T cells in an effort to minimize GVHD. Methods of T-cell depletion include antibody affinity column, antibody-coated plates, antibody-coated plates and soybean lectin, antibody + toxin, immunomagnetic beads, CD34 affinity column plus sheep red blood cell resetting, and T-cell receptor alpha / beta depletion.*
2/27/19	2402: Disease Classification	Add	Added (in red below) additional instruction for question 165: *Indicate the number of times the recipient has been in the disease phase reported in question 163.*
2/27/19	Appendix J: Reporting Comorbidities	Remove	Removed (struck out below) incorrect instruction for reporting Cerebrovascular disease comorbidities: *Any history of:* • *Trasient ischemic attack* • *Cerebrovascular accident / stroke* • *Subarachnoid, ~~hemoorhage; do not include~~ subdural, epidural, or intraparenchymal hemorrhage*
2/27/19	2402: Disease Classification	Add	Added (in red below) additional instruction for question 277: ***Question 277: Was a PET (or combination PET / CT) scan performed? (at last evaluation prior to the start of the preparative regimen / infusion)*** *Report "Yes" and go to question 278 if a PET scan was performed within three months prior to the start of the preparative regimen / infusion. Combination PET / CT may also be reported, but a CT scan alone should not be captured here. Centers may report a PET scan performed during the most recent line of therapy so long as it is the most recent scan and was done within noted period. Report "No" and go to question 283 if a PET scan was not performed within this period.*
2/27/19	2116: PCD Post-HCT	Add	Added (in red below) additional instruction for question 61: *However, bisphosphonate therapy (e.g., Zometa) should not be reported as planned therapy since it is universally administered to myeloma patients. Additionally, supportive care such as Denosumab (e.g., Prolia) should not be reported as planned therapy.*
3/19/19	2450: Post-TED	Add	Added the following red warning box instruction (in red below) below question 75 to clarify when to use the CCR option in the Disease Assessment at the Time of Best Response to HCT section of the Post-TED (2450) form: Continued Complete Remission (CCR) should be reported for all patients who were already in CR at the start of the preparative regimen.

Questions, feedback, or requests may be submitted directly on the manual website using the Feedback Feature at the bottom of each page. For more information on how to submit feedback, click here.