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.

<table>
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| 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. |
| 2/27/19    | 2006: Post-TED                  | Modify              | Added additional instruction (in red below) regarding T-Cell depletion under questions 73-95: |

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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.