CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

April 2019 Forms Instruction Manual Updates

In case you missed them, here are the changes made to the Forms Instruction Manual during the month of April. 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
4/11/19	2450: Post-TED	Modify	Updated the instruction on how to report Dexamethasone if given for disease relapse or progression post-HCT. Dexamethasone should be reported as "Other Systemic Therapy," not "Other Therapy."
4/19/19	2450: Post-TED	Modify	Provided additional instruction and examples for reporting the current disease status in Questions 237-238.
4/19/19	Amyloidosis Response Criteria	Modify	Modified the following sections (removed text is struck out below, added text is in red) of the Amyloidosis Response Criteria: ***Partial Response***: • *≥ 50% reduction in current serum monoclonal protein levels > 0.5 g/dL* • *≥ 50% reduction in current ~~urine light chain~~ urine m-protein levels > 100 mg/day with a visible peak* • *≥ 50% reduction in current free light chain levels > 10mg/dL* ***Renal Response***: • *≥ 50% decrease of at least 0.5 g/day (500mg/24hr) in 24-hour urine protein of > 0.5 g/day (500mg/24hr) pre-treatment and* • *Creatinine clearance or serum creatinine must not have worsened by ≥ 25% over baseline* *If only serum creatinine is obtained, an estimated creatinine clearance can be calculated using the following formula:* ***Estimated Creatinine Clearance** = [(140 – Age (years)) * Weight (kg)] / [72 * Serum Creatinine (mg/dL)]* *The calculation should be multiplied by 0.85 for women.*
4/19/19	Appendix D: How to Distinguish Infusion Types	Modify	Updated the Co-infusion (with HCT) section to reflect updated cellular therapy forms (added text in red below): *When reporting co-infusions, the Cellular Therapy Product form (4003) and Cellular Therapy Infusion form (4006) is are required for all recipients. The HCT Infusion form (2006) will capture information regarding the product intended for engraftment.*
4/19/19	Appendix J: Reporting Comorbidities	Add	Added (in red below) instruction for reporting a cardiac comorbidity: *The presence of one or more of the following:* • *Any history of coronary artery disease (one or more vessels requiring medical treatment, stent, or bypass),* • *Any history of myocardial infarction, or* • *Any history of congestive heart failure , or* • *LVEF ≤ 50% (or a shortening fraction (SF) of < 26% for pediatric cases) on most recent evaluation prior to the start*

			of the preparative regimen Also added instruction to the blue not box describing Hepatic and Renal comorbidities to clarify what to report based on laboratory values closest to the start of the preparative regimen.
4/19/19	2131: ID Post-HCT	Modify	Updated the engraftment statuses for questions 167 – 172. The engraftment status have been updated (struck out text has been deleted and red text has been added) as follows: • *Predominantly or completely donor (≥80% donor chimerism)* • *Mixed chimerism (5 – 79% ~~80%~~ donor)* • *Only host cells detected (<5% donor)*
4/19/19	Waldenstrom's Macroglobulinemia Response Criteria	Add	Added (in red below) the following text for the Progressive Disease response criteria: ***Progressive disease (PD)*** • *≥ 25% increase in serum monoclonal IgM spike from lowest nadir on serum electrophoresis and/or* • *Progression of clinically significant findings or symptoms (for example, anemia, adenopathy, constitutional symptoms, amyloidosis, etc.) attributed to WM/LPL*
4/19/19	Multiple Myeloma Response Criteria	Modify	Modified (struck out text has been deleted and red text has been added) the response criteria for Relapse from CR: ***Relapse from CR*** *Requires one or more of the following:* • *Reappearance of serum or urine M-protein by immunofixation ~~or~~ electrophoresis; and/or* • *Development of ≥ 5% plasma cells in the bone marrow; and/or* • *Appearance of any other sign of progression (e.g., new plasmacytoma, lytic bone lesion, hypercalcemia).* *Positive immunofixation alone in a patient previously classified as achieving a complete response should **not** be considered a relapse.*
4/26/19	2814: Indication for CRID Assignment	Modify	Version 3 of the 2814: Indication for CRID Assignment section of the Forms Instructions Manual released. Version 3 corresponds to revision 4 of the Form 2814.
4/26/19	2540: Tepadina Supplemental Data Collection	Modify	Version 2 of the 2540: Tepadina Supplemental Data Collection section of the Forms Instruction Manual released. Version 2 corresponds to revision 2 of the Form 2540.

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.