

PCD/Multiple Myeloma Post-HCT Data Manual Change History through 3/31/15

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.1	11/21/2013	Modify	Changed "Form 2016" to "Form 2116" in document header
2.1	11/21/2013	Add	Added "(Revision 3)" to title of document
2.2	03/28/2014	Add	Added a Note to Question 3: <i>NOTE: Currently there is an issue on Form 2016 regarding the number of plasma cells required for CR. CR requires less than (but not equal to) 5 % plasma cells in the bone marrow.</i>
2.2	03/28/2014	Modify	Question 61 – modified text to read: <i>Indicate if the recipient received therapy post-transplant for any reason other than relapse or progressive disease since the date of last report. If "yes," continue with question 62. If "no" or "unknown," continue with question 402 100.</i>
2.3	06/01/2014	Modify	Updated formatting to match CIBMTR brand standards
2.3	06/01/2014	Modify	Updated explanatory text in question 61 to read: <i>Do not include any treatment administered as a result of relapse or progression.</i> <i>For the purposes of this question, a line of therapy is one or more cycles of a defined treatment program given to a patient with no progression of disease in between. A new line of therapy may be started for reasons including drug toxicities, planned changes to medications, etc. starts when a new agent is (or agents are) added/changed due to relapse, progression, and/or toxicity If a drug dose was changed due to toxicity, do not report this as a new line of therapy; however, if a drug is stopped and a new one started due to toxicity, report this as a new line of therapy.</i>

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2.4	07/11/2014	Add	<p>Added text to Multiple Myeloma Disease Reponse Criteria for VGPR:</p> <p>One or more of the following must be present:</p> <ul style="list-style-type: none"> • Serum and urine M-protein detectable by immunofixation but not on electrophoresis • $\geq 90\%$ reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. <p><i>If the serum and urine M-protein are not measurable (i.e., do not meet the following criteria at time of diagnosis):</i></p> <ul style="list-style-type: none"> • Serum M-protein ≥ 1 g/dL • Urine M-protein ≥ 200 mg/24 hours; <p><i>then a $\geq 90\%$ decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria.</i></p> <p><i>VGPR requires two consecutive assessments (by the same method) made at any time before the institution of any new therapy. If radiographic studies were performed, there must be no known evidence of new or progressive bone lesions. Radiographic studies are not required to satisfy VGPR requirements.</i></p>