

PCD/Multiple Myeloma Pre-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	Formatted Table 3.: Indented " B one Disease (lytic bone lesions and/or advanced osteoporosis)" to match rest of text.
2.1	11/21/2013	Add	Added "(Revision 3)" to title of document
2.2	03/28/2014	Add	Added a Note to Questions 229 and 363: <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	Questions 9-118 – modified explanatory text preceding questions: <i>For questions 9-118, report values obtained at diagnosis or prior to the first treatment for the plasma cell disorder for which the transplant was performed. If testing is performed multiple times prior to the start of the first treatment, report the last test before the start of treatment. If the recipient has a plasma cells disorder other than plasma cell leukemia, do not answer questions 15-18, as they apply only to the diagnosis of PCL.</i>
2.3	06/01/2014	Modify	Updated formatting to match CIBMTR brand standards

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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>
2.5	08/22/2014	Modify	<p>In Question 31, the calcium criteria for Durie-Salmon was changed from ≤ 12 to < 10.5 mg/dL to match the case report form.</p> <ul style="list-style-type: none"> • Serum calcium normal (< 10.5 mg/dL)