

## 2116: PCD Post-HCT

The Plasma Cell Disorder Post-HCT Data Form is one of the Comprehensive Report Forms. This form captures plasma cell disorder post-HCT data such as: disease assessment at the time of best response, hematologic and organ parameters at the time of best response, post-HCT therapy, disease status at the time of evaluation for this reporting period, and current status of amyloidosis for this reporting period.

This form must be completed for all recipients whose primary disease reported on the Pre-TED Disease Classification Form (Form 2402) is "Multiple myeloma/plasma cell disorder (PCD)." The Post-HCT Plasma Cell Disorder form must be completed in conjunction with each Post-HCT follow-up form (Forms 2100, 2200, and 2300). This form is designed to capture specific data occurring within the timeframe of each reporting period (i.e., between day 0 and day 100 for Form 2100; between day 100 and the six-month date of contact for six-month follow-up for Form 2200; and between the date of contact for the six-month follow-up and the date of contact for the one-year follow-up for Form 2200, etc.).

[Q1-2: Disease Specificity](#)

[Q3-34: Disease Assessment at the Time of Best Response to HCT](#)

[Q35-60: Hematologic and Organ Parameters at the Time of Best Response](#)

[Q61-101: Post-HCT Therapy](#)

[Q102-136: Disease Status at the Time of Evaluation for this Reporting Period](#)

[Q137-162: Current Status of Amyloidosis for this Reporting Period](#)

### Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please [click here](#) or reference the retired manual section on the [Retired Forms Manuals](#) webpage.

Date	Manual Section	Add/Remove/Modify	Description
2/27/19	<a href="#">2116: PCD Post-HCT</a>	Add	Added (in red below) additional instruction for question 61: <i>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.</i>
12/	<a href="#">2116: PCD</a>	Remove	Removed the following blue note box instruction (struck out below) for

21/ 2018	<a href="#">Post-HCT</a>		<p>questions 30 and 126 regarding Flow Cytometry reporting for Myeloma. These assessments can now be reported in the same way as all other disease assessments.</p> <p><del><b>An exception of the note above applies to multiple myeloma. If the flow cytometry assessment has &lt; 5% malignant plasma cells, this result should not be reported because the result is not reliable; if no other cytogenetic or FISH assessments were performed, report "no."</b> However, if the flow cytometry assessment found <math>\geq</math> 5% malignant plasma cells, this should be reported as evidence of disease.</del></p>
3/19/ 18	2116: PCD Post-HCT	Add	Added Current Disease Status note box above the instructions for question 137.
3/19/ 18	Comprehensive Disease Specific Manuals	Add	<p>Added the following instruction for applicable post-infusion disease-specific forms where current disease status is asked (2110, 2111, 2112, 2113, 2114, 2115, 2116, 2118, 2119).</p> <p><i>The center does not need to repeat all disease-specific assessments (biopsies, scans, labs) each reporting period in order to complete current disease status data fields. Once a particular disease status is achieved, the center can continue reporting that disease status (based on labs / clinical assessments) until there is evidence of relapse / progression.</i></p>
2/13/ 18	2116: PCD Post-HCT	Add	Added <b>Daratumumab</b> note box to the instructions for questions 69-90.
1/24/ 18	2116: PCD Post-HCT	Add	Added <b>Not Applicable Amyloidosis</b> note box to the instructions for question 135.
1/24/ 18	2116: PCD Post-HCT	Remove	<p>Removed text (struck out below) from the instructions for question 96.</p> <p><del><i>If the recipient had amyloidosis or POEMS syndrome, but no evidence of myeloma, select "Not Applicable (Amyloidosis with no evidence of myeloma)." .</i></del></p>
1/24/ 18	2116: PCD Post-HCT	Add	Added <b>Amyloidosis</b> note box to the instructions for questions 96.
2/24/ 17	Comprehensive Disease- Specific Manuals	Modify	Updated explanations of triggers for disease inserts to refer to the primary disease reported on the Pre-TED Disease Classification Form (Form 2402) instead of the Pre-TED Form (Form 2400)
6/12/ 15	2116: PCD Post-HCT	Add	Added instruction for <b>METHOD</b> and <b>DATE</b> reporting in the <a href="#">Q102-136: Disease Status at the Time of Evaluation for this Reporting Period</a> section just prior to <a href="#">question 126</a> . See text for full detail.
5/29/ 15	2116: PCD Post-HCT	Modify	<p>Added text for clarification in questions <a href="#">18</a> and <a href="#">114</a>:</p> <p>(total in g/dL of monoclonal protein) x (total urine volume) = urinary M-protein/24 hours</p> <p>(0.145 g/dL of monoclonal protein) x (1500 mL total urine) x (<b>1 dL/100 mL</b>) = 2.175 g/24 hours</p>
5/29/ 15	2116: PCD Post-HCT	Add	<p>Added an informational bubble in questions <a href="#">30</a> and <a href="#">126</a>:</p> <p>Flow cytometry is a technique that can be performed on blood, bone marrow, or tissue preparations where cell surface markers can be</p>

			quantified on cellular material. Currently the CIBMTR forms do not contain fields to capture flow cytometry data. Since the sensitivity of flow cytometry is similar to that of FISH assays, flow cytometry data should be reported in question 31 [or 127]. <b>An exception to the note above applies to multiple myeloma.</b> If the flow cytometry assessment has < 5% malignant plasma cells, this result should not be reported because the result is not reliable; if no other cytogenetic or FISH assessments were performed, report “no.” However, if the flow cytometry assessment found $\geq$ 5% malignant plasma cells, this should be reported as evidence of disease.
5/29/ 15	2116: PCD Post-HCT	Add	Added text to questions <a href="#">67-68</a> : Indicate if the number of cycles is “known” or “unknown.” If known, report the number of cycles the recipient received <b>during the reporting period</b> for the line of therapy being reported in question 68. If the therapy is not given in cycles or the number of cycles is not known, select “unknown” and continue with question 69.
5/29/ 15	2116: PCD Post-HCT	Modify	Modified explanatory text for questions <a href="#">96</a> and <a href="#">135</a> : If the recipient had amyloidosis <b>or POEMS syndrome</b> , but no evidence of myeloma, select “Not Applicable ( <b>POEMS or</b> Amyloidosis with no evidence of myeloma)”

*Last modified: 2019/02/27*

## Q1-2: Disease Specificity

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### Question 1: Was the recipient transplanted for or do they have a history of amyloidosis?

This form is designed to best capture data related to the recipient's specific plasma cell disorder. Select "yes" to indicate that the recipient was transplanted for or has a history of amyloidosis and continue with question 2. Questions appropriate for amyloidosis will become active if completing the form electronically. Select "no" to indicate that the recipient was not transplanted for and does not have a history of amyloidosis and continue with question 3. When completing the form electronically, selecting no will prevent questions specific to amyloidosis from becoming active and only questions relating to non-amyloidosis plasma cell disorders will be shown.

### Question 2: Did the recipient have features of multiple myeloma?

If the recipient had multiple myeloma in addition to amyloidosis, select "yes" & continue with question 3. If the recipient did not have multiple myeloma in addition to amyloidosis, select "no" and continue with question 4.

*Last modified: 2018/04/26*

## Q3-34: Disease Assessment at the Time of Best Response to HCT

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Best response is based on response to the HCT and does NOT include response to therapy given for disease relapse or progression post-HCT.

- If the HCT was planned as part of initial therapy for a recipient with no disease progression or relapse at any time prior to HCT, determine the best response by comparing to the disease assessment at time of original diagnosis.
- If the HCT was performed later in the disease course for a patient who has not received any chemotherapy within 6 months of HCT or has untreated relapse or progression, determine the best response to HCT by comparing the disease status immediately prior to the start of the preparative regimen.
- If the patient had a disease progression or relapse of disease at any time prior to HCT, and was treated to reduce the myeloma burden prior to the start of the preparative regimen, determine the best response to HCT by comparing to the disease evaluation at the time of relapse or progression. In other words, the baseline is reset to the time of relapse or progression.

This comparison is meant to capture the best disease status in response to HCT that occurred in the reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous interval, confirm the best response and check the box to indicate “date previously reported.” This option is only applicable on report forms for the six-month reporting interval and beyond.

**Question 3: Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease):**

The intent of this question is to determine the best overall response to HCT, which could include any response to planned therapy post-HCT, or to therapy given for maintenance or prophylaxis. (DO NOT include any response to treatment given for relapsed or progressive disease.) This is assessed in each reporting period. When evaluating the best response, determine the disease status within the reporting period and compare it to all previous post-HCT reporting periods. If the response in the current reporting period is the best response to date, report the disease status established within this reporting period. If a better response was established in a previous reporting period, report the previously established disease status. See question 4 to indicate that this disease status was previously reported.

! Currently there is an issue on Form 2116 regarding the number of plasma cells required for CR. CR requires less than (but not equal to) 5% plasma cells in the bone marrow.

See the [Multiple Myeloma Response Criteria](#) section for multiple myeloma and solitary plasmacytoma disease status definitions. See [Plasma Cell Leukemia Response Criteria](#) for plasma cell leukemia disease status definitions.

**At any response level, if some but not all criteria are met, the best response should be downgraded to next lower level of response.**

**Example:** A myeloma patient is transplanted in PR. In the 100-day reporting period all the CR criteria (3% plasma cells in the bone marrow, SPEP/UPEP negative) are met with the exception of a positive immunofixation on serum and urine (two disease assessments were performed in the reporting period indicating a positive immunofixation); in this case nCR should be reported as the best response to transplant.

! The percentage of plasma cells in the bone marrow aspirate and/or biopsy may also be identified on a flow cytometry report. A flow cytometry report may **NOT** be used to confirm CR (e.g., < 5% plasma cells in the bone marrow).

\* Only report the best response to HCT from all reporting periods. See Examples below.

**Example 1:** A recipient with myeloma goes to transplant having established a PR prior to transplant, achieves a VGPR during the first 100 days, and then progresses during the six-month reporting period. The best response to transplant should be reported as “VGPR” on all subsequent forms. See below:

Reporting Period	Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	PR	—	—
100-Days Post-HCT	VGPR	VGPR	<i>[date of 1st confirmatory labs]</i>
6-Months Post-HCT	Progression	VGPR	Previously reported
1-Year Post-HCT	PR	VGPR	Previously reported

**Example 2:** A recipient with myeloma goes to transplant having established a CR prior to transplant, maintains the response after transplant, and then relapses within the six-month reporting period. The best response to transplant would be reported as “CR” for all subsequent reporting periods. See below:

Reporting Period	Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	CR	—	—
100-Days Post-HCT	CR	CR	<i>[date of labs that first confirmed a continued CR]</i>
6-Months Post-HCT	Relapsed	CR	Previously reported
1-Year Post-HCT	VGPR	CR	Previously reported

**Example 3:** A recipient with myeloma goes to transplant having established a PR prior to transplant and maintains the response throughout the 100-day reporting period. During the six-month reporting period, the recipient progresses and begins unplanned therapy to treat the worsening disease. During the one-year reporting period, the recipient achieves VGPR. The best response to transplant occurred during the 100-day reporting period because response to unplanned therapy is not captured using this set of questions. See below:

Reporting Period	Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	PR	—	—
100-Days Post-HCT	PR	PR	<i>[date of labs that first confirmed a continued PR]</i>
6-Months Post-HCT	Progression	PR	Previously reported
1-Year Post-HCT	VGPR	PR	Previously reported

**Example 4:** A recipient with myeloma goes into transplant having established VGPR prior to transplant and maintains the response throughout the 100-day reporting period. During the six-month reporting period, the recipient achieves a CR and is placed on maintenance therapy. During the one-year reporting period the recipient maintains the CR. The best response to transplant occurred in the six-month reporting period. See below:

Reporting Period	Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	VGPR	—	—
100-Days Post-HCT	VGPR	VGPR	<i>[date of labs that first confirmed a continued VGPR]</i>
6-Months Post-HCT	CR	CR	<i>[date of labs that first confirmed CR]</i>
1-Year Post-HCT	CR	CR	Previously reported

Include response to any post-HCT treatment planned as of Day 0. If post-transplant therapy is given as prophylaxis or maintenance for recipients in CR, or as preemptive therapy for recipients with minimal

residual disease, consider this “planned therapy” even if this was not documented prior to the transplant. Bisphosphonate therapy (e.g., Zometa) should not be considered when making this determination. **Do not include any treatment administered as a result of relapse or progression.**

#### Question 4: Was the date of best response previously reported?

Indicate if the best response was reported on a previous post-HCT plasma cell disorder form (Form 2116). If “yes,” continue with question 35. If “no,” continue with question 5.

If the best response is the same as the pre-transplant disease status, select “no,” report the date of the first assessment that confirmed the ongoing disease status post-HCT in question 5.

#### Question 5: Date assessed:

Enter the date the best response first began. In other words, report the date of the first assessment, **not** the date of the second confirmatory assessment. Report the date the blood/urine was collected for the laboratory evaluations (e.g., SPEP/UPEP, serum/urine immunofixation) or report the date the bone marrow was collected for pathologic examination.



Questions are often raised about how to report the best response and the date it first began when there is not a second assessment within the same reporting period. One way to approach this is if you have a second assessment that confirms the best disease response from the next reporting period available at the time the form is being completed, you can report the best disease response and the date the response first began. If you don't have a second assessment to confirm the new disease status response at the time a form is being completed, you must report the disease response that was previously confirmed.

**Example 1:** A recipient with myeloma goes into transplant having established a PR prior to transplant. During the 100-day reporting period, the recipient achieves a VGPR. However, the second disease assessment to confirm the VGPR was not performed until one month later (which is in the next reporting period). Those results are available at the time the Day 100 disease form is being completed. The best response to transplant would be reported as “VGPR” with the date it first began in the 100-day reporting period. The recipient maintains the VGPR in the six-month reporting period. The best response to transplant would be reported as “VGPR” with the date as “previously reported” in the six-month reporting period.

**Example 2:** A recipient with myeloma goes into transplant having established a PR prior to transplant. During the 100-day reporting period, the recipient achieves a VGPR. However a second disease assessment to confirm the VGPR response is not available when the form is being completed. The best response to transplant would be reported as “PR” with the date continuing disease response was

confirmed.

**Example 3:** A recipient with myeloma goes into transplant having established a PR prior to transplant. During the 100-day reporting period, the recipient achieves a VGPR. However a second disease assessment to confirm the VGPR response is not available when the form is being completed. The best response to transplant would be reported as “PR” with the date continuing disease response was confirmed in the 100-day reporting period. When completing the six-month form, a second disease assessment to confirm a VGPR response is available. The best response to transplant would be reported as “VGPR.” However, since the VGPR first began during the Day 100 reporting period, an error correction needs to be completed to update the disease status and date first achieved on the Day 100 report.



- Under normal circumstances, a marrow aspirate is used to obtain the differential cell count, review morphology of the cells, and perform cytogenetic studies, flow cytometry, etc. A biopsy is obtained to evaluate the overall cellularity of the marrow. In the case of myeloma, the marrow plasma cells tend to be a patchy infiltrate rather than a diffuse infiltrate as in the case of acute leukemia. Therefore, it is possible that the plasma cell numbers may vary between the aspirate and the biopsy.
- The percentage of plasma cells in the bone marrow aspirate and/or biopsy may also be identified on a flow cytometry report. A flow cytometry report may NOT be used as source documentation when reporting the data for questions 6-9.
- If the bone marrow pathology report states a range for plasma cells, enter the average of the range rounded to the nearest whole number (e.g., if 0-5%, enter 3%).
- If the report states > 90% plasma cells, enter 91% on the form.
- If the report states a marrow packed with plasma cells or sheets of plasma cells, report 99% on the form.
- If the report states < 5% plasma cells, enter 4% on the form.

#### Questions 6-7: Plasma cells in bone marrow aspirate:

Indicate whether the percentage of plasma cells in the bone marrow **aspirate** was “known” or “unknown” at the time of best response to transplant. If “known,” report the percentage of plasma cells in the bone marrow aspirate documented on the pathology report in question 7. If “unknown,” continue with question 8.

#### Questions 8-9: Plasma cells in bone marrow biopsy:

Indicate whether the percentage of plasma cells in the bone marrow **biopsy** was “known” or “unknown” at the time of best response to transplant. If “known,” report the percentage of plasma cells in the bone marrow biopsy documented on the pathology report in question 9. If “unknown,” continue with question 10.

#### Questions 10-11: Serum monoclonal protein (M-spike): (only from electrophoresis)

Monoclonal gammopathy is defined as the increased production of one type of immunoglobulin by a single

clone of cells. The abnormal protein produced is called paraprotein or M-protein. Indicate whether the serum monoclonal immunoglobulin was “known” or “unknown” at the time of best response to transplant. If “known,” report the value and unit of measure documented on the laboratory report in question 11. If “unknown” or “not applicable,” continue with question 12.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

#### **Questions 12: Serum immunofixation:**

Serum immunofixation is a laboratory technique that detects and types monoclonal antibodies or immunoglobulins in the blood. If “known” at the time of best response to transplant, continue with question 13. If “unknown” or “not applicable,” continue with question 16.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

#### **Question 13: Specify monoclonal immunoglobulin result:**

If monoclonal immunoglobulin is “present,” continue with question 14. If “absent,” continue with question 16.

#### **Question 14: Original monoclonal bands:**

Indicate “yes” if the original monoclonal band was present or “no” if it was not present.

#### **Question 15: New monoclonal (or oligoclonal) bands:**

Indicate “yes” if a new monoclonal (or oligoclonal) band was present or “no” if it was not present.

#### **Questions 16-17: Total urinary protein excretion:**

Indicate whether the amount of urinary protein was “known” or “unknown” at the time of best response to transplant. The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value in question 17. If “unknown,” continue with question 18.

#### **Questions 18-19: Urinary monoclonal protein (M-spike):**



##### **Urinary Monoclonal Protein**

Questions 18-19 are intended to capture the 24-hour urine monoclonal protein results, not the 24-hour protein excretion (questions 16-17 capture the total protein secretion/24 hours). The results will be reported as XX g or XX g/dL. If the value is reported in XX g/dL, it can be multiplied by the volume of the urine to determine the 24-hour urine monoclonal protein. Do not report immunofixation results here.

**Example:**

(total in g/dL of monoclonal protein) x (total urine volume) = **urinary M-protein/24 hours**  
(0.145 g/dL of monoclonal protein) x (1500 mL total urine) x (1 dL/100 mL) = **2.175 g/24 hours**

Indicate whether the amount of urinary monoclonal protein was “known” or “unknown” at the time of best response to transplant. The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value in question 19. If “unknown” or “not applicable,” continue with question 20.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

**Question 20: Urinary immunofixation:**

Urine immunofixation is a laboratory technique that detects and types monoclonal antibodies or immunoglobulins in the urine. Indicate if the results of urinary immunofixation were “known” or “unknown” at the time of best response to transplant. If “known,” continue with question 21. If “unknown” or “not applicable,” continue with question 24.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

**Question 21: Specify monoclonal immunoglobulin result:**

If monoclonal immunoglobulin was “present,” continue with question 22. If “absent,” continue with question 24.

**Question 22: Original monoclonal bands:**

Indicate “yes” if the original monoclonal band was present or “no” if it was not present.

**Question 23: New monoclonal (or oligoclonal) bands:**

Indicate “yes” if a new monoclonal (or oligoclonal) band was present or “no” if it was not present.

**Questions 24-25: Serum free light chains – κ (kappa):**

Indicate whether the serum κ (kappa) free light chain level was “known” or “unknown” at the time of best response to transplant. This value should reflect the quantity of serum free light chains, not a quantification of total light chains. If “known,” report the value and unit of measure documented on the laboratory report in question 25 and continue with question 26. If “unknown” or “not applicable,” continue with question 27.

**Question 26: Upper limit of normal for κ free light chain:**

Indicate the upper limit of normal for κ (kappa) free light chains value and the unit of measure used at your

institution.

**Questions 27-28: Serum free light chain –  $\lambda$  (lambda):**

Indicate whether the serum  $\lambda$  (lambda) free light chain level was “known” or “unknown” at the time of best response to transplant. This value should reflect the quantity of serum free light chains, not a quantification of total light chains. If “known,” report the value and unit of measure documented on the laboratory report in question 28 and continue with question 29. If “unknown” or “not applicable,” continue with question 30.

**Question 29: Upper limit of normal for  $\lambda$  free light chain:**

Indicate the upper limit of normal for  $\lambda$  (lambda) free light chains value and the unit of measure used at your institution.

**Question 30: Was the disease status assessed by cytogenetic testing (conventional or FISH)?**



**Flow Cytometry**

Flow cytometry is a technique that can be performed on blood, bone marrow, or tissue preparations where cell surface markers can be quantified on cellular material. Currently the CIBMTR forms do not contain fields to capture flow cytometry data. Since the sensitivity of flow cytometry is similar to that of FISH assays, flow cytometry data should be reported in question 31.

Cytogenetic assessment involves testing blood or bone marrow for the presence of a known cytogenetic abnormality that reflects the recipient’s disease. FISH is categorized with cytogenetics. Although often used for finding specific features in DNA, FISH is not as sensitive as molecular methods, even though the markers identified may be the same.

If a cytogenetic assessment was performed to assess disease status at the time of best response to transplant, select “yes” and continue with question 31.

If a cytogenetic assessment was not performed, check “no” and continue with question 35.

**Question 31: Was the disease status assessed via FISH?**

FISH, fluorescence *in situ* hybridization, is a sensitive technique that assesses a large number of cells. This technique uses special probes that recognize and bind to fragments of DNA commonly found in plasma cell disorders. These probes are mixed with cells from the recipient’s blood. A fluorescent “tag” is then used to visualize the binding of the probe to the diseased cells.

Indicate if FISH studies were obtained at the time of best response to transplant. If FISH studies were

obtained, select “yes” and continue with question 32.

If no FISH studies were obtained or it is unknown if FISH studies were performed, select “no” and continue with question 33.

**Question 32: Date assessed:**

Enter the date of FISH assessment at the time of best response. Report the date the sample was collected for the laboratory.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

**Question 33: Was the disease status assessed via conventional cytogenetics?**

Cytogenetics is the study of chromosomes. Cytogenetic assessment involves testing blood or bone marrow for the presence of a known chromosomal abnormality that reflects the recipient’s disease. Cytogenetics may also be referred to as karyotyping or g-banding.

Indicate if cytogenetic studies were obtained at the time of best response to transplant. If cytogenetic studies were obtained, select “yes” and continue with question 34.

If no cytogenetic studies were obtained or it is unknown if chromosome studies were performed, select “no” and continue with question 35.

**Question 34: Date assessed:**

Enter the date of conventional cytogenetic assessment at the time of best response. Report the date the sample was collected for the laboratory.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

*Last modified: 2018/12/21*

## Q35-60: Hematologic and Organ Parameters at the Time of Best Response (for Amyloid Patients only)

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Complete questions 35-60 for amyloid patients only. If diagnosis was other than amyloidosis or there is no history of it, continue with question 61.

The response time for amyloidosis tends to occur well after transplant, so the “best response” to transplant may not occur within the first 100 days. The intent of this question is to determine the best overall response to HCT, which could include any response to planned therapy post-HCT, or to therapy given for maintenance or prophylaxis. DO NOT include any response to treatment given for relapsed or progressive disease. This is assessed in each reporting period. When evaluating the best response, determine the disease status within the reporting period and compare it to all previous post-HCT reporting periods. If the response in the current reporting period is the best response to date, report the disease status established within this reporting period. If a better response was established in a previous reporting period, report the previously established disease status.

### Question 35: Specify the recipient’s best hematologic response to the HCT:

Indicate the recipient’s best hematologic response to HCT to date. See [Amyloidosis Response Criteria](#) for disease status definitions.

If best response is CR, PR, NR, SD, or progressive disease, continue with question 36.

If the recipient’s hematologic status was not assessed during the reporting period, select “not assessed” and continue with question 38. “Not applicable” should rarely, if ever, be chosen.

### Questions 36-37: Date assessed:

Indicate if the date the best hematologic response to transplant was assessed is “known,” “unknown,” or “previously reported.” If the hematologic response is known, report the date in question 37. If the date is unknown, select “unknown” and continue with question 38. If the best response to transplant was already reported in a previous reporting period, select “previously reported” and continue with question 38.

### Question 38: Specify the recipient’s best cardiac response to the HCT:

Indicate the recipient’s best cardiac response to HCT to date. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient's cardiac status was not assessed during the reporting period, select "not assessed." If the recipient never had evidence of cardiac involvement in their disease, select "not applicable."

**Questions 39-40: Date assessed:**

Indicate if the date the best cardiac response to transplant was assessed is "known," "unknown," or "previously reported." If the cardiac response is known, report the date in question 40. If the date is unknown, select "unknown" and continue with question 41. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 41.

**Question 41: Was there clinical improvement in GI involvement in response to the HCT (decrease in diarrhea)?**

Indicate if there was clinical improvement of GI involvement to date. Judgment is required by a clinician to determine if there is evidence of improvement. If "yes" or "no," continue with question 42. If "unknown," continue with question 44.

**Questions 42-43: Date assessed:**

Indicate if the date the GI involvement was assessed is "known," "unknown," or "previously reported." If the date the GI response was assessed is known, report the date in question 43. If the date is unknown, select "unknown" and continue with question 44. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 44.

**Question 44: Specify the recipient's best hepatic response to the HCT:**

Indicate the recipient's best hepatic response to HCT to date. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient's hepatic status was not assessed during the reporting period, select "not assessed." If the recipient never had evidence of hepatic involvement in their disease, select "not applicable."

**Questions 45-46: Date assessed:**

Indicate if the date the best hepatic response to transplant was assessed is "known," "unknown," or "previously reported." If the hepatic response is known, report the date in question 46. If the date is unknown, select "unknown" and continue with question 47. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 47.

**Question 47: Specify the best response of the autonomic neuropathy to the HCT:**

Indicate the recipient's best autonomic neuropathy response to HCT to date. See [Amyloidosis Response](#)

[Criteria](#) for disease status definitions.

If the recipient's autonomic neuropathy was not assessed during the reporting period, select "not assessed."  
If the recipient never had evidence of disease related autonomic neuropathy, select "not applicable."

**Questions 48-49: Date assessed:**

Indicate if the date the best autonomic neuropathy response to transplant was assessed is "known," "unknown," or "previously reported." If the autonomic neuropathy response is known, report the date in question 49. If the date is unknown, select "unknown" and continue with question 50. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 50.

**Question 50: Specify the best response of peripheral neuropathy to the HCT:**

Indicate the recipient's best peripheral neuropathy response to HCT to date. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient's peripheral neuropathy was not assessed during the reporting period, select "not assessed."  
If the recipient never had evidence of disease-related peripheral neuropathy, select "not applicable."

**Questions 51-52: Date assessed:**

Indicate if the date the best peripheral neuropathy response to transplant was assessed is "known," "unknown," or "previously reported." If the peripheral neuropathy response is known, report the date in question 52. If the date is unknown, select "unknown" and continue with question 53. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 53.

**Question 53: Specify the recipient's best renal response to the HCT:**

Indicate the recipient's best renal response to HCT to date. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient's renal status was not assessed during the reporting period, select "not assessed." If the recipient never had evidence of renal involvement in their disease, select "not applicable."

**Questions 54-55: Date assessed:**

Indicate if the date the best renal response to transplant was assessed is "known," "unknown," or "previously reported." If the renal response is known, report the date in question 55. If the date is unknown, select "unknown" and continue with question 56. If the best response to transplant was already reported in a

previous reporting period, select “previously reported” and continue with question 56.

**Questions 56-57: Did any other system respond to the HCT?**

Indicate if any other system was assessed for response to HCT. If the recipient had other site involvement reported in questions 179-185 of the Pre-HCT Plasma Cell Disorder form (Form 2016) and that site was assessed, the response to HCT must be reported here, even if there was no response.

Indicate the involved system/site in question 57.

**Question 58: Specify best response to HCT for this system:**

Indicate if the site’s/system’s best response to transplant was “response,” “no response/stable disease,” “progressive disease,” or “not applicable.”

**Questions 59-60: Date assessed:**

Indicate if the date the other site’s/system’s best response to transplant was assessed is “known,” “unknown,” or “previously reported.” If the other site’s/system’s response is known, report the date in question 60. If the date is unknown, select “unknown” and continue with question 61. If the best response to transplant was already reported in a previous reporting period, select “previously reported” and continue with question 61.

*Last modified: 2015/02/23*

## Q61-101: Post-HCT Therapy

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### Question 61: Was therapy given since the date of last report for reasons other than relapse or progressive disease? (Include any maintenance and consolidation therapy.):

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 100.

Recipients are generally transplanted under a specific protocol that defines the systemic therapy the recipient is intended to receive as a preparative regimen prior to the HCT; the infection and GVHD prophylaxis to be administered pre- and/or post-HCT; and any systemic therapy, radiation, and/or other treatments to be administered post-HCT as planned (or maintenance) therapy. Planned (maintenance or consolidation) therapy is given to help prolong a remission. This protocol may be either a research protocol or standard-of-care protocol and should be referred to when completing this section.

Additionally, if post-transplant therapy is given as prophylaxis or maintenance for recipients in CR, or as preemptive therapy for recipients with minimal residual disease, consider this “planned therapy” even if this was not documented prior to the transplant. However, bisphosphonate therapy (e.g., Zometa) should not be reported as a 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.

Do not include any treatment administered as a result of relapse or progression.

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. 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.

**Example 1:** A recipient with myeloma goes into transplant having established nCR prior to transplant and maintains the response throughout the 100-day reporting period. During the six-month reporting period, the recipient achieves a CR and is placed on maintenance lenalidomide therapy at 15 mg/day.

**Example 2:** A recipient with myeloma goes into transplant having established PR prior to transplant and achieves a VGPR in the 100-day reporting period. During the six-month reporting period, the recipient maintains the VGPR and is placed on maintenance lenalidomide therapy at 10 mg/day. During the one-year reporting period, the recipient progresses and unplanned treatment is initiated. Only the maintenance

lenalidomide would be reported in questions 61-99.

### **Question 62: Systemic therapy:**

Systemic therapy may be injected into a vein or given orally, and is delivered to the whole body via the blood stream. If “yes,” continue with question 63. If “no,” continue with question 91.

### **Questions 63-64: Date therapy started:**

Indicate if the date the therapy started was “known” or “unknown.” If known, enter the date the recipient began this line of therapy in question 64. If the start date was reported on a previous report, report the same date again when the start/stop dates overlap reporting periods. If “unknown,” continue with question 65.

If the start date is partially known (i.e., the recipient started treatment in mid-July 2010), use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

### **Questions 65-66: Date therapy stopped:**

Indicate if the date the therapy stopped is “known” or “unknown.” If the stop date is known and the recipient is receiving therapy administered in cycles, report the date the recipient started the last cycle for this line of therapy in question 66. If “unknown,” continue with question 67.

If the recipient is receiving therapy administered on a daily basis (e.g., lenalidomide therapy at 10 mg/day) report the last date the recipient received the line of therapy.

If therapy won't be stopped until the next reporting period or later, question 65 should be left blank. Override the error with “UA,” unable to answer.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

### **Questions 67-68: Number of cycles:**

Systemic therapy is usually administered in cycles with rest periods between the cycles. This enables cancer cells to be attacked at vulnerable times and provides healthy cells adequate time to recover from the damage. A cycle can last one or more days and may repeat weekly, bi-weekly, or monthly. A systemic therapy course may consist of multiple cycles.

Indicate if the number of cycles is “known” or “unknown.” If known, report the number of cycles the recipient received during the reporting period for the line of therapy being reported in question 68. If the therapy is not given in cycles or the number of cycles is not known, select “unknown” and continue with question 69.

**Questions 69-90: Specify systemic therapy:****Daratumumab**

If the recipient received Daratumumab (Darzalex), please report this drug in “Other systemic therapy.”

Treatments vary based on protocol and in most cases are administered in the outpatient setting. A treatment may consist of a single drug or a combination of drugs. Additionally, the drugs may be administered on one day, over consecutive days, or continuously. Indicate “yes” or “no” for each chemotherapy treatment drug administered for the line of therapy being reported. Do not leave any yes/no responses blank. If the recipient received a chemotherapy treatment that is not listed, check “yes” for “other systemic therapy” and specify the treatment in question 90. Report the generic name of the agent, not the brand name.

**Question 91: Radiation therapy:**

Radiation therapy uses high-energy radiation to kill cancer cells. For multiple myeloma, external beam radiation is used most frequently. In this method, a beam of radiation is delivered to a specific part of the body, such as a lytic lesion or plasmacytoma. Indicate if the recipient received radiation during this reporting period post-HCT. If “yes,” continue with question 92. If “no,” continue with question 96.

**Questions 92-93: Date therapy started:**

Indicate if the date the therapy started is “known” or “unknown.” If known, enter the date the line of radiation therapy began in question 93.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

**Questions 94-95: Date therapy stopped:**

Indicate if the date the therapy started is “known” or “unknown.” If known, enter the date the line of radiation therapy ended in question 95.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

**Question 96: Best response to line of therapy:****Amyloidosis**

If the recipient's primary disease is Amyloidosis (without evidence of myeloma), report Complete Remission (CR) if the CR criteria for all involved organs are met (see [Amyloidosis Response Criteria](#)). If the disease status is anything other than CR, report "Not applicable" for question 96. The form will be updated to remove "(Amyloidosis with no evidence of myeloma)" in the near future. This is a change from the previous instruction which asked centers to report "Not applicable" for all amyloidosis cases, regardless of disease response.

Indicate the best response to the line of therapy. See the [Multiple Myeloma Response Criteria](#) section for multiple myeloma and solitary plasmacytoma disease status definitions. See [Plasma Cell Leukemia Response Criteria](#) for plasma cell leukemia disease status definitions.

For more information on determining what baseline values to use to determine best response, see [Appendix G](#).

**At any response level, if some but not all criteria are met, the best response should be downgraded to next lower level of response.**

The percentage of plasma cells in the bone marrow aspirate and/or biopsy may also be identified on a flow cytometry report. A flow cytometry report may **NOT** be used to confirm CR (e.g., < 5% plasma cells in the bone marrow).

If the disease response following this line of therapy is unknown, select "unknown."

If the recipient had POEMS syndrome, but no evidence of myeloma, select "Not Applicable."

#### **Question 97: Date response established:**

Any response requires two consecutive assessments (of the same labs, where applicable based on response criteria) made at any time before the start of a new therapy. Enter the date the best response to the line of therapy was established. In other words, report the date of the first assessment, not the date of the second confirmatory assessment. Report the date the blood/urine was collected for the laboratory evaluations (e.g., SPEP/UPEP, serum/urine immunofixation) or report the date the bone marrow was collected for pathological evaluation.

#### **Question 98: Did disease relapse/progress following this line of therapy?**

Indicate "yes" if a relapse or progression occurred following the line of therapy being reported and continue with question 99. Documentation of relapse or progression requires two consecutive assessments (of the same labs, where applicable based on response criteria) made at any time before classification as relapse or progression, and/or the start of a new therapy. Indicate "no" if the recipient did not relapse or progress

following this line of therapy and continue with question 100.

See [Multiple Myeloma Response Criteria](#) for progressive disease and Relapse from CR disease status definitions.

#### **Question 99: Date of relapse/progression:**

Enter the date the relapse or progression was established following the line of therapy. Report the date the blood/urine was collected for the laboratory evaluations (e.g., SPEP/UPEP, serum/urine immunofixation) or report the date the bone marrow was collected for pathological evaluation. However, if there was not a second assessment (where applicable by response criteria) obtained prior to the start of new therapy, report the date the new therapy started as the date of relapse/progression. Continue with question 100.

Copy questions 62-99 to report more than one line of therapy.



It is possible that the relapse or progression would be reported twice if already reported in question 98. Question 98 is asking about relapse or progression following any planned/maintenance therapy. Question 100 is asking about relapse or progression at any time, regardless of whether therapy was given or not.

#### **Question 100: Has the disease relapsed or progressed since the date of last report?**

Indicate “yes” if a relapse or progression occurred during the reporting period and continue with question 101. Documentation of relapse or progression requires two consecutive assessments (of the same labs, where applicable based on response criteria) made at any time before classification as relapse or progression, **and/or** the start of a new therapy. Indicate “no” if the recipient did not relapse or progress during the reporting period and continue with question 102.

See [Multiple Myeloma Response Criteria](#) for progressive disease and Relapse from CR disease status definitions.

#### **Question 101: Specify the date of disease relapse or progression:**

Enter the date the relapse or progression was established following the line of therapy. Report the date the blood/urine was collected for the laboratory evaluations (e.g., SPEP/UPEP, serum/urine immunofixation) or report the date the bone marrow was collected for pathological evaluation. However, if there was not a second assessment (where required) obtained prior to the start of new therapy, report the date the new therapy started as the date of relapse/progression. Continue with question 102.

*Last modified: 2019/02/27*

## Q102-136: Disease Status at the Time of Evaluation for this Reporting Period

- ✿ • Under normal circumstances, the marrow **aspirate** is used to obtain the differential cell count, review morphology of the cells, and to perform cytogenetic studies, flow cytometry, etc. The biopsy is obtained to evaluate the overall cellularity of the marrow. In the case of myeloma, the marrow plasma cells tend to be a patchy infiltrate rather than a diffuse infiltrate as in the case of acute leukemia. Therefore, it's possible that the plasma cell numbers may vary between the aspirate and biopsy.
- The percentage of plasma cells in the bone marrow aspirate and/or biopsy may also be identified on a flow cytometry report. A flow cytometry report may NOT be used as source documentation when reporting the data for questions 102-105.
- If the bone marrow pathology report states a range for plasma cells, enter the average of the range rounded to the nearest whole number (e.g., if 0-5%, enter 3%).
- If the report states > 90% plasma cells, enter 91% on the form.
- If the report states a marrow packed with plasma cells or sheets of plasma cells, report 99% on the form.
- If the report states < 5% plasma cells, enter 4% on the form.

### Questions 102-103: Plasma cells in bone marrow aspirate:

Indicate if the percentage of plasma cells in the bone marrow **aspirate** was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the percentage of plasma cells in bone marrow **aspirate** documented on the pathology report in question 103. If “unknown,” continue with question 104.

### Questions 104-105: Plasma cells in bone marrow biopsy:

Indicate whether the percentage of plasma cells in the bone marrow **biopsy** was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the percentage of plasma cells in the bone marrow **biopsy** documented on the pathology report in question 105. If “unknown,” continue with question 106.

### Questions 106-107: Serum monoclonal protein (M-spike): (only from electrophoresis)

Monoclonal gammopathy is defined as the increased production of one type of immunoglobulin by a single clone of cells. The abnormal protein produced is called paraprotein or M-protein. Indicate whether the serum monoclonal immunoglobulin was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the value and unit of measure documented on the laboratory report in question 107. If “unknown” or “not applicable,” continue with question 108.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

#### Questions 108: Serum immunofixation:

Serum immunofixation is a laboratory technique that detects and types monoclonal antibodies or immunoglobulins in the blood. If “known” at the time of evaluation for this reporting period, continue with question 109. If “unknown” or “not applicable” continue with question 112.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

#### Question 109: Specify monoclonal bands:

If monoclonal immunoglobulin was “present,” continue with question 110. If “absent,” continue with question 112.

#### Question 110: Original monoclonal bands:

Indicate “yes” if the original monoclonal band was present or “no” if it was not present.

#### Question 111: New monoclonal (or oligoclonal) bands:

Indicate “yes” if a new monoclonal band (or oligoclonal) was present or “no” if not present.

#### Questions 112-113: Total urinary protein excretion:

Indicate whether the amount of urinary protein was “known” or “unknown” at the time of evaluation for this reporting period. The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value in question 113. If “unknown” or “not applicable,” continue with question 114.

#### Questions 114-115: Urinary monoclonal protein (M-spike):



#### Urinary Monoclonal Protein

Questions 114-115 are intended to capture the 24-hour urine monoclonal protein results, not the 24-hour protein excretion (questions 112-113 capture the total protein secretion/24 hours). The results will be reported as XX g or XX g/dL. If the value is reported in XX g/dL, it can be multiplied by the volume of the urine to determine the 24-hour urine monoclonal protein. Do not report immunofixation results here.

#### Example:

(total in g/dL of monoclonal protein) x (total urine volume) = **urinary M-protein/24 hours**  
 (0.145 g/dL of monoclonal protein) x (1500 mL total urine) x (1 dL/100 mL) = **2.175 g/24 hours**

Indicate whether the amount of urinary monoclonal protein was “known” or “unknown” at the time of evaluation for this reporting period. The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value in question 115 and continue with question 116. If “unknown” or “not applicable,” continue with question 116.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

#### **Question 116: Urinary immunofixation:**

Urine immunofixation is a laboratory technique that detects and types monoclonal antibodies or immunoglobulins in the urine. Indicate if the results of urinary immunofixation were “known” or “unknown” at the time of evaluation for the reporting period. If “known,” continue with question 117. If “unknown” or “not applicable,” continue with question 120.

“Not applicable” is appropriate for recipients with non-secretory myeloma.

#### **Question 117: Specify monoclonal immunoglobulin result:**

If monoclonal immunoglobulin was “present,” continue with question 118. If “absent,” continue with question 120.

#### **Question 118: Original monoclonal bands:**

Indicate “yes” if the original monoclonal band was present or “no” if it was not present.

#### **Question 119: New monoclonal (or oligoclonal) bands:**

Indicate “yes” if a new monoclonal (or oligoclonal) band was present or “no” if it was not present.

#### **Questions 120-121: Serum free light chains – κ (kappa):**

Indicate whether the serum κ (kappa) free light chain level was “known” or “unknown” at the time of evaluation for the reporting period. This value should reflect the quantity of serum **free** light chains, not a quantification of total light chains. If “known,” report the value and unit of measure documented on the laboratory report in question 121. If “unknown” or “not applicable,” continue with question 123.

#### **Question 122: Upper limit of normal for κ free light chain:**

Indicate the upper limit of normal for κ (kappa) free light chains value and unit of measure used at your institution.

**Questions 123-124: Serum free light chain –  $\lambda$  (lambda):**

Indicate whether the serum  $\lambda$  (lambda) free light chain level was “known” or “unknown” at the time of evaluation for the reporting period. This value should reflect the quantity of serum **free** light chains, not a quantification of total light chains. If “known,” report the value and unit of measure documented on the laboratory report in question 124. If “unknown” or “not applicable,” continue with question 126.

**Question 125: Upper limit of normal for  $\lambda$  free light chain:**

Indicate the upper limit of normal for  $\lambda$  (lambda) free light chains value and the unit of measure used at your institution.

**Disease Status at Time of Evaluation for this Reporting Period**

Review the instruction below regarding method and date reporting for this section.

**METHOD**

This section should reflect the recipient’s most recent disease assessment. Not all recipients have cytogenetic or FISH abnormalities identified to monitor disease status. If no disease assessments exist for the applicable method, check “no.”

Cytogenetic assessments may be performed for many reasons post-transplant, including monitoring for secondary malignancy. If the recipient did not have any identified cytogenetic or FISH abnormalities at diagnosis or during their pre-transplant course, and post-HCT follow-up assessments continue to show that no abnormalities are detected, report “no” for these assessment data fields. However, if routine post-HCT cytogenetic or FISH assessments identify a new abnormality associated with the recipient’s disease process, begin reporting those assessments; report the assessment identifying the new abnormality, as well as all subsequent assessments for the abnormality by that method.

If the recipient had cytogenetic or FISH abnormalities prior to transplant, ensure that post-HCT assessments of the applicable method are reported.

**Example:** The recipient has IGH abnormalities identified by FISH testing prior to transplant; however, they had a normal karyotype on all pre-transplant assessments. Post-transplant, FISH studies incorporating an IGH probe should be reported; conventional cytogenetic studies would not be reported (answer question 131 as “no”) unless the recipient develops abnormalities associated with their disease detectable by conventional cytogenetics; the study identifying the new abnormalities and all subsequent conventional cytogenetic studies would be reported.

**DATE**

If more than one test in the same assessment category is done on different days, report the date of the most definitive diagnostic assessment within a reasonable time frame of the date of contact (approximately 30 days). If there was only a single assessment performed within the reporting period, it should be reported, even if it was more than 30 days prior to the date of contact.

**Example:** The recipient continues to have a positive serum immunofixation; however, two days after their latest immunofixation, they have a bone marrow biopsy performed. The bone marrow biopsy does not show evidence of disease. Report the date of the serum immunofixation, since it is the most disease specific given that it continues to reveal evidence of disease in a patient who is clearly not disease free.

### Question 126: Was the disease status assessed by cytogenetic testing (conventional or FISH)?

#### Flow Cytometry

Flow cytometry is a technique that can be performed on blood, bone marrow, or tissue preparations where cell surface markers can be quantified on cellular material. Currently the CIBMTR forms do not contain fields to capture flow cytometry data. Since the sensitivity of flow cytometry is similar to that of FISH assays, flow cytometry data should be reported in question 127.

Cytogenetic assessment involves testing blood or bone marrow for the presence of a known cytogenetic abnormality that reflects the recipient's disease. FISH is categorized with cytogenetics. Although often used for finding specific features in DNA, FISH is not as sensitive as molecular methods, even though the markers identified may be the same.

If a cytogenetic assessment was performed at the time of evaluation for this reporting period, select "yes" and continue with question 127.

If no cytogenetic assessments were performed, check "no" and continue with question 135.

### Question 127: Was the disease status assessed via FISH?

FISH, fluorescence *in situ* hybridization, is a sensitive technique that assesses a large number of cells. This technique uses special probes that recognize and bind to fragments of DNA commonly found in plasma cell disorders. These probes are mixed with cells from the recipient's blood. A fluorescent "tag" is then used to visualize the binding of the probe to the diseased cells.

Indicate if FISH studies were obtained at the time of evaluation for this reporting period. If FISH studies were obtained, select "yes" and continue with question 128.

If no FISH studies were obtained, select "no" and continue with question 131.

**Question 128: Date assessed:**

Enter the date of FISH assessment at the time of evaluation for the reporting period. Report the date the sample was collected for the laboratory.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions. Guidelines for Completing Forms](#).

**Question 129: Was disease detected?**

Indicate if evidence of disease was detected on the sample sent for FISH assessment. If FISH results were consistent with evidence of disease, check “yes” and continue with question 130.

If FISH results were not consistent with evidence of disease, check “no” and continue with question 131.

**Question 130: Was the status considered a disease relapse or progression?**

Indicate if the FISH abnormalities were considered to be relapsed or progressive disease. Criteria for cytogenetic relapse or progression are established by clinical judgment, and should reflect the clinical decision of the transplant physician. A recipient may be reported to have cytogenetic relapse or progression even in the setting of hematologic CR. Criteria for complete remission are based on hematologic (biochemical markers) and pathologic (marrow) characteristics and are independent of cytogenetic markers of disease.

If the recipient has FISH abnormalities that the physician considers to be consistent with cytogenetic relapse, check “yes” and continue with question 131.

If the recipient has FISH abnormalities that the physician does not consider to be consistent with molecular relapse, check “no” and continue with question 131.

**Question 131: Was the disease status assessed via conventional cytogenetics?**

Cytogenetics is the study of chromosomes. Cytogenetic assessment involves testing blood or bone marrow for the presence of a known chromosomal abnormality that reflects the recipient’s disease. Cytogenetics may also be referred to as karyotyping or g-banding.

Indicate if cytogenetic studies were obtained at the time of evaluation for this reporting period. If cytogenetic studies were obtained, select “yes” and continue with question 132.

If no cytogenetic studies were obtained, select “no” and continue with question 135.

**Question 132: Date assessed:**

Enter the date of conventional cytogenetic assessment at the time of evaluation for this reporting period. Report the date the sample was collected for the laboratory.

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions, Guidelines for Completing Forms](#).

**Question 133: Was disease detected?**

Indicate if evidence of disease was detected on the sample sent for conventional cytogenetic assessment. If conventional cytogenetic results were consistent with evidence of disease, check “yes” and continue with question 134.

If conventional cytogenetic results were not consistent with evidence of disease, check “no” and continue with question 135.

**Question 134: Was the status considered a disease relapse or progression?**

Indicate if the conventional cytogenetic abnormalities were considered to be relapsed or progressive disease. Criteria for cytogenetic relapse or progression are established by clinical judgment, and should reflect the clinical decision of the transplant physician. A recipient may be reported to have cytogenetic relapse or progression even in the setting of hematologic CR. Criteria for complete remission are based on hematologic (biochemical markers) and pathologic (marrow) characteristics, and are independent of cytogenetic markers of disease.

If the recipient has conventional cytogenetic abnormalities that the physician considers to be consistent with cytogenetic relapse, select “yes” and continue with question 135.

If the recipient has conventional cytogenetic abnormalities that the physician does not consider to be consistent with molecular relapse, check “no” and continue with question 135.

**Question 135: What was the disease status?****Not Applicable for Amyloidosis**

Report “Not Applicable (Amyloidosis with no evidence of myeloma)” for question 135 if the recipient’s primary disease is Amyloidosis. Current status of amyloidosis data are captured in questions 137-161.

Report the disease status at the time of evaluation for this reporting period. See the [Multiple Myeloma](#)

[Response Criteria](#) section for multiple myeloma and solitary plasmacytoma disease status definitions. See [Plasma Cell Leukemia Response Criteria](#) for plasma cell leukemia disease status definitions.

**At any response level, if some but not all criteria are met, the disease status should be downgraded to next lower level of response.**

The percentage of plasma cells in the bone marrow aspirate and/or biopsy may also be identified on a flow cytometry report. A flow cytometry report may **NOT** be used to confirm CR (e.g., < 5% plasma cells in the bone marrow).

If the disease response prior to transplant is unknown, select “unknown” and continue with the signature lines.

If the recipient had amyloidosis or POEMS syndrome, but no evidence of myeloma, select “Not Applicable (POEMS or Amyloidosis with no evidence of myeloma)”

The center does not need to repeat all disease-specific assessments (biopsies, scans, labs) each reporting period in order to complete current disease status data fields. Once a particular disease status is achieved, the center can continue reporting that disease status (based on labs / clinical assessments) until there is evidence of relapse / progression.

**Question 136: Date assessed:**

Enter the date of the most recent disease evaluation. Report the date the blood/urine was collected for the laboratory evaluations (e.g., SPEP/UPEP, serum/urine immunofixation) or report the date the bone marrow was collected for pathological evaluation. A PET scan may be used **if** a PET scan was previously obtained and **only** in limited circumstances (e.g., plasmacytomas, lytic lesions).

If the exact date is not known, use the process described for reporting partial or unknown dates in [General Instructions. Guidelines for Completing Forms](#).

*Last modified: 2018/12/21*

# Q137-162: Current Status of Amyloidosis for this Reporting Period (for Amyloid Patients Only)

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Complete questions 137-162 for Amyloid patients only. If diagnosis was other than amyloidosis or there is no history of it, continue with signature line.

## \* Current Disease Status

The center does not need to repeat all disease-specific assessments (biopsies, scans, labs) each reporting period in order to complete current disease status data fields. Once a particular disease status is achieved, the center can continue reporting that disease status (based on labs / clinical assessments) until there is evidence of relapse / progression.

Specify the recipient's current disease status for each of the following hematologic and organ systems:

### Question 137: Specify the recipient's current hematologic status:

Indicate the recipient's current hematologic status at the time of evaluation for this reporting period. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient's hematologic status was CR, PR, NR, or progressive disease, continue with question 138.

If the recipient's hematologic status was not assessed during the reporting period, select "not assessed" and continue with question 140. "Not applicable" should rarely, if ever, be chosen.

### Questions 138-139: Date assessed:

Indicate if the date of hematologic assessment is "known" or "unknown." If the date of assessment for hematologic status is known, report the date in question 139. If the date is unknown, select "unknown" and continue with question 140.

### Question 140: Specify the recipient's current cardiac status:

Indicate the recipient's current cardiac status at the time of evaluation for this reporting period. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient's cardiac status was not assessed during the reporting period, select "not assessed." If the

recipient never had evidence of cardiac involvement in their disease, select “not applicable.”

**Questions 141-142: Date assessed:**

Indicate if the date of cardiac assessment is “known” or “unknown.” If the date of assessment for cardiac status is known, report the date in question 142. If the date is unknown, select “unknown” and continue with question 143.

**Question 143: Was there clinical improvement in GI involvement since the date of last report?**

Indicate if there was clinical improvement of GI involvement at the time of evaluation for this reporting period. Judgment is required by a clinician to determine if there is evidence of improvement. If “yes” or “no,” continue with question 144. If “unknown,” continue with question 146.

**Questions 144-145: Date assessed:**

Indicate if the date the GI involvement was assessed is “known” or “unknown.” If the date the GI response was assessed is known, report the date in question 145. If the date is unknown, select “unknown” and continue with question 146.

**Question 146: Specify the recipient’s current hepatic status:**

Indicate the recipient’s current hepatic status at the time of evaluation for this reporting period. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient’s hepatic status was not assessed during the reporting period, select “not assessed.” If the recipient never had evidence of hepatic involvement in their disease, select “not applicable.”

**Questions 147-148: Date assessed:**

Indicate if the date of hepatic assessment is “known” or “unknown.” If the date of assessment for hepatic status is known, report the date in question 148. If the date is unknown, select “unknown” and continue with question 149.

**Question 149: Specify the current status of autonomic neuropathy:**

Indicate the recipient’s current autonomic neuropathy status at the time of evaluation for this reporting period. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient’s autonomic neuropathy was not assessed during the reporting period, select “not assessed.” If the recipient never had evidence of disease related autonomic neuropathy, select “not applicable.”

**Questions 150-151: Date assessed:**

Indicate if the date of autonomic neuropathy assessment is “known” or “unknown.” If the date of assessment for autonomic neuropathy status is known, report the date in question 151. If the date is unknown, select “unknown” and continue with question 152.

**Question 152: Specify the current status of peripheral neuropathy:**

Indicate the recipient’s current peripheral neuropathy status at the time of evaluation for this reporting period. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient’s peripheral neuropathy was not assessed during the reporting period, select “not assessed.” If the recipient never had evidence of disease related peripheral neuropathy, select “not applicable.”

**Questions 153-154: Date assessed:**

Indicate if the date of autonomic neuropathy assessment is “known” or “unknown.” If the date of assessment for autonomic neuropathy status is known, report the date in question 154. If the date is unknown, select “unknown” and continue with question 155.

**Question 155: Specify the recipient’s current renal status:**

Indicate the recipient’s current renal status at the time of evaluation for this reporting period. See [Amyloidosis Response Criteria](#) for disease status definitions.

If the recipient’s renal status was not assessed during the reporting period, select “not assessed.” If the recipient never had evidence of renal involvement in their disease, select “not applicable.”

**Questions 156-157: Date assessed:**

Indicate if the date of hepatic assessment is “known” or “unknown.” If the date of assessment for hepatic status is known, report the date in question 157. If the date is unknown, select “unknown” and continue with question 158.

**Questions 158-159: Was any other system assessed for current status?**

Indicate if any other system was assessed at the time of evaluation for the reporting period. If the recipient had other site involvement reported in questions 179-185 of the Pre-HCT Plasma Cell Disorder form (Form 2016) and that site was assessed, the status should be reported here.

Indicate the involved system/site in question 159.

**Question 160: Specify the current status of this system:**

Indicate if the recipient's current response is "response," "no response/stable disease," "progressive disease," or "not applicable."

**Questions 161-162: Date assessed:**

Indicate if the date the other site/system was assessed at the time of evaluation for the reporting period is "known" or "unknown." If the other site/system response is known, report the date in question 162. If the date is unknown, select "unknown" and continue with the signature lines.

*Last modified: 2018/03/19*