2116: PCD Post-Infusion

The Plasma Cell Disorder Post-HCT Data Form is one of the Comprehensive Report Forms. This form captures plasma cell disorder (PCD) 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 (Form 2100). This form is designed to capture specific data occurring within the timeframe of each reporting period (i.e., between day 0 and day 100; between day 100 and the six-month date of contact for six-month follow-up; and between the date of contact for the six-month follow-up and the date of contact for the one-year follow-up, etc.).

Links to Sections of the Form

Q1-2: Disease Specificity
Q3-53: Disease Assessment at the Time of Best Response to HCT or Cellular Therapy
Q54-109: Organ Parameters of Amyloidosis at the Time of Best Response
Q110-141: POEMS Syndrome Assessment at the Time of Best Response
Q142-210: Post-Infusion Therapy
Q211-252: Disease Status at the Time of Evaluation for this Reporting Period
Q253-311: Current Status of Amyloidosis for this Reporting Period
Q312-343: Current Status of POEMS Syndrome 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
10/ 23/ 2020	2116: PCD Post-Infusion	Modify	Provided clarification and additional examples on how to report next generation flow (NGF) in questions 39-42.
10/1/ 2020	2116: PCD Post-	Add	Instructions added on when to use the “unknown” and “not applicable” options for question 190: *Indicate if the recipient received maintenance therapy after treatment for relapse / progression since the date of the last report. If “yes,” continue with*

	Infusion		*question 191. If "no," continue with question 211. If it is not known or not possible to determine if the recipient was placed on subsequent maintenance therapy after treatment for relapse / progression, then select "Unknown" and proceed to question 211. This option should be used sparingly and only in cases when it is truly unknown as to whether maintenance therapy was given within the reporting period after treatment for relapse / progression. Indicate "Not Applicable" if the recipient did not receive treatment for relapse / progression. Please see the example below: Example: A recipient was in CR and was receiving maintenance Revlimid. Due to health issues, the maintenance therapy was briefly discontinued; however, the recipient's IgG reappeared during this time. The patient was not treated for relapse and eventually continued on with the Revlimid maintenance. In this case, question 190 would be answered as "Not Applicable" because he was not treated for relapse but instead continued on with his maintenance therapy.*
6/9/2020	2116: PCD Post-Infusion	Modify	Update question 2 with the correct instructions: Indicate if the recipient had a concurrent or preceding plasma cell disorder. Many recipients progress to symptomatic myeloma from a preceding condition or have a concurrent plasma cell disorder, such as amyloidosis. This question will be auto-populated from the ~~Plasma Cell Disorders (PCD) Pre-Infusion (2016)~~ Disease Classification (2402) Form.
5/8/2020	2116: PCD Post-Infusion	Add	Added guidance to questions 124-125 to document unit of measure to the nearest tenth.
5/8/2020	2116: PCD Post-Infusion	Add	Added guidance to questions 329-330 to document unit of measure to the nearest tenth.
5/8/2020	2116: PCD Post-Infusion	Add	Added guidance to questions 326-327 to document unit of measure to the nearest tenth.
5/8/2020	2116: PCD Post-Infusion	Add	Added guidance to questions 127-128 to document unit of measure to the nearest tenth.
3/27/2020	2116: PCD Post-Infusion	Modify	Updated question numbers found in guidance for answering questions 54 and 91 in the section Q54-109: Organ Parameters of Amyloidosis at the Time of Best Response.
3/27/2020	2116: PCD Post-Infusion	Modify	Updated question numbers found in guidance for answering questions 256 and 293 in the section Q253-311: Current Status of Amyloidosis for this Reporting Period.
3/27/2020	2116: PCD Post-Infusion	Add	Added sentence for guidance on answering question 251 in that says **This question will not be enabled if the primary disease for transplant is monoclonal gammopathy of renal significance (MGRS).** in the section Q211-252: Disease Status at the Time of Evaluation for this Reporting Period.
3/27/2020	2116: PCD	Add	Added sentence for guidance on answering question 3 in that says **This question will not be enabled if the primary disease for transplant is monoclonal**

	Post-Infusion		**gammopathy of renal significance (MGRS).** in the section Q3-53: Disease Assessment at the Time of Best Response to HCT or Cellular Therapy.
3/23/2020	2116: PCD Post-Infusion	Add	Added information about the LV strain percentage in the Q253-311: Current Status pf Amyloidosis for this Reporting Period section for questions 265-266.
3/23/2020	2116: PCD Post-Infusion	Add	Added information about the LV strain percentage in the Q54-109: Organ Parameters of Amyloidosis at the Time of Best Response section for questions 63-64.
1/24/2020	2116: PCD Post-Infusion	Modify	Version 3 of the 2016: Plasma Cell Disorders (PCD) Post-Infusion Data section of the Forms Instruction Manual released. Version 3 corresponds to revision 4 of the Form 2116.

Last modified: Nov 11, 2020

Q1-2: Disease Specificity

Question 1: Specify the multiple myeloma / plasma cell disorder (PCD) classification:

Specify the indication for transplant. This question will be auto-populated from the Pre-TED Disease Classification and Characteristics (2402) Form.

Question 2: Specify preceding / concurrent disorder (check all that apply):

Indicate if the recipient had a concurrent or preceding plasma cell disorder. Many recipients progress to symptomatic myeloma from a preceding condition or have a concurrent plasma cell disorder, such as amyloidosis. This question will be auto-populated from the Disease Classification (2402) Form.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q3-53: Disease Assessment at the Time of Best Response to HCT or Cellular Therapy

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 or cellular therapy was planned as part of initial therapy for a recipient with no disease progression or relapse at any time prior to HCT or cellular therapy, determine the best response by comparing to the disease assessment at the time of initial diagnosis.
- If the HCT or cellular therapy was performed later in the disease course for a patient who has not received any chemotherapy within 6 months of HCT or cellular therapy or has untreated relapse or progression, determine the best response to HCT or cellular therapy 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 or cellular therapy and was treated to reduce the myeloma burden prior to the start of the preparative regimen, determine the best response to HCT or cellular therapy 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 or cellular therapy 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 reporting interval, confirm the best response and indicate that the date was previously reported (question 4).

Question 3: For all recipients with primary disease multiple myeloma / plasma cell disorder (PCD) classifications, excluding Amyloidosis, compared to the disease status prior to the preparative regimen, what was the best hematologic response to HCT or cellular therapy since the date of last report? (Include response to any therapy given for post-HCT or post-cellular therapy maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease):

> ! This question will be answered for recipients whose primary disease for infusion includes all plasma cell disorders **except** amyloidosis. If amyloidosis was reported as the primary disease for infusion (question 1), skip questions 3-5 and continue with question 6.

The intent of this question is to determine the best overall response to HCT or cellular therapy, which could include any response to planned therapy post-HCT or cellular therapy, 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 or post-cellular therapy 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.

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.

This question will not be enabled if the primary disease for transplant is monoclonal gammopathy of renal significance (MGRS).

If the recipient was already in CR at the start of the preparative regimen, select “Continued complete response (CCR),” and continue with question 4.

! Continued complete response (CCR) should be reported for all patients who were already in CR at the start of the preparative regimen.

✻ Only report the best response to HCT or cellular therapy from all reporting periods. See Examples below.

Example 1: 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 VGPR should be reported as the best response to transplant.

Example 2: 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	Current Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	PR	—-	—-
100-Days Post-HCT	VGPR	VGPR	[date of 1st confirmatory labs]
6-Months Post-HCT	Progression	VGPR	Previously Reported
1-Year Post-HCT	PR	VGPR	Previously Reported

Example 3: 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 “CCR” for all subsequent reporting periods. See below:

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

Example 4: 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	Current Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	PR	—-	—-
100-Days Post-HCT	PR	PR	[date of latest labs that confirmed a continued PR]
6-Months Post-HCT	Progression	PR	Previously Reported
1-Year Post-HCT	VGPR	PR	Previously Reported

Example 5: 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	Current Disease Status	Q1. Best Response	Q5. Date Assessed
Pre-transplant	VGPR	—-	—-
100-Days Post-HCT	VGPR	VGPR	[date of latest labs that confirmed a continued VGPR]
6-Months Post-HCT	CR	CR	date of labs that first confirmed CR
1-Year Post-HCT	CR	CR	Previously Reported

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," and the recipient has a preceding / concurrent diagnosis of amyloidosis (question 2) continue with question 6. If not, continue with question 142. If "no," continue with question 5.

If the best response achieved during the 100-day reporting period is the same as the pre-transplant disease status, select "no," report the latest disease assessment that confirmed the ongoing disease status post-HCT in question 5. For all subsequent reporting periods, report "yes," until a better disease response is achieved.

If the recipient's pre-transplant disease status was "Continued complete response (CCR)," select "no," report the date of the first assessment that confirmed the ongoing CR in question 5 on the 100-day form. For all subsequent reporting periods, report "yes."

Question 5: Date assessed:

Enter the date the best response first began. 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.

If the recipient has a preceding / concurrent diagnosis of amyloidosis (question 2) continue with question 6. If not, continue with question 9.

> ✻ 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 of the latest disease assessment.

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 of the latest disease assessment 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.

Question 6: For recipients with primary disease or concurrent / history of Amyloidosis, compared to the disease status prior to the preparative regimen, what was the best hematologic response to HCT or cellular therapy since the date of last report? (Include response to any therapy given for post-HCT or post-cellular therapy maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease):

> ! Complete questions 6-8 for amyloidosis patients only. If amyloidosis was not reported as the primary disease for infusion (question 1) or as a preceding / concurrent disorder (question 2), skip to question 9.

The intent of this question is to determine the best overall response to HCT or cellular therapy, which could include any response to planned therapy post-HCT or post-cellular therapy, 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 or post-cellular therapy 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 7 to indicate that this disease status was previously reported.

See the Amyloidosis Response Criteria section for disease status definitions.

If the recipient was already in CR at the start of the preparative regimen, select “Continued complete response (CCR),” and continue with question 7.

> ! Continued complete response (CCR) should be reported for all patients who were already in CR at the start of the preparative regimen.

Question 7: 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 54. If “no,” continue with question 8.

If the best response achieved during the 100-day reporting period is the same as the pre-transplant disease status, select “no,” report the latest disease assessment that confirmed the ongoing disease status post-HCT in question 8. For all subsequent reporting periods, report “yes” until a better disease response is achieved.

If the recipient’s pre-transplant disease status was “Continued complete response (CCR),” select “no,” report the date of the first assessment that confirmed the ongoing CR post-HCT in question 8 on the 100-day form. For all subsequent reporting periods, report “yes.”

Question 8: Date assessed:

Enter the date the best response first began and continue with question 9. 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.

Laboratory Assessments at the Time of Best Response

Questions 9-33 refer to disease assessments performed at the time of best response for their primary disease for infusion (question 5 or 8). Report testing performed closest to the date of best response and within the time windows in the Disease Assessment Time Windows table.

Disease Assessment Time Windows

Follow-Up Form	Approximate Range
100 Day	+/- 15 days of date of best response (question 5 or 8)
6 Month	+/- 15 days of date of best response (question 5 or 8)
Annual	+/- 30 days of date of best response (question 5 or 8)

Questions 9-10: Serum creatinine:

Indicate whether the serum creatinine was “known” or “unknown” at the time of best response. If “known,” report the laboratory value and unit of measure documented on the laboratory report in question 10 and continue with question 11. If “unknown,” continue with question 12.

Questions 11: Upper limit of serum creatinine:

Indicate the upper limit of normal for serum creatinine value found on the laboratory report.

Questions 12-13: Serum monoclonal protein (M-spike) (only from electrophoresis):

Monoclonal gammopathy is defined as the increased production of abnormal immunoglobulins. 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. If “known,” report the value and unit of measure documented on the laboratory report in question 13. If “unknown,” continue with question 14. Report “not applicable” for recipients with non-secretory myeloma.

Do not report immunofixation results here.

Question 14: Serum immunofixation:

Serum immunofixation is a laboratory technique that detects and types monoclonal antibodies or immunoglobulins in the blood. If “known,” continue with question 15. If “unknown,” continue with question 17. Report “not applicable” for recipients with non-secretory myeloma.

Question 15: Original monoclonal bands:

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

Question 16: New monoclonal (or oligoclonal) bands:

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

Questions 17-18: Serum free light chains – κ (kappa):

Indicate whether the serum κ (kappa) free light chain level at the time of best response is “known” or “unknown.” 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 18 and continue with question 19. If “unknown” or “not applicable,” continue with question 20. Report “not applicable” for recipients with non-secretory myeloma.

Question 19: 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 found on the laboratory report.

Questions 20-21: Serum free light chains – λ (lambda):

Indicate whether the serum λ (lambda) free light chain level at the time of best response is “known” or “unknown.” This value should reflect the quantity of serum free light chains, not a quantification of total light chains. If “known,” report the laboratory value and unit of measure documented on the laboratory report in question 21. If “unknown” or “not applicable,” continue with question 23. Report “not applicable” for recipients with non-secretory myeloma.

Question 22: Upper limit of normal for λ free light chains:

Indicate the upper limit of normal for λ (lambda) free light chains value and the unit of measure found on the laboratory report.

> **Urinary Monoclonal Protein**
> Questions 23-24 are intended to capture the 24-hour urine monoclonal protein results, not the 24-hour protein excretion. The results will be reported as XX g or XX g/dL. If the value is reported in XX g/dL, it should be multiplied by the volume of the urine to determine the 24-hour urine monoclonal protein. Do not report immunofixation results here.

Questions 23-24: Urinary monoclonal protein (M-spike) / 24 hours:

Indicate whether the amount of urinary monoclonal protein at the time of best response is “known” or “unknown.” The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value and unit of measure documented on the laboratory report in question 24. If “unknown” or “not applicable,” continue with question 25. Report “not applicable” for recipients with non-secretory myeloma.

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**

Question 25: 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 at the time of best response are “known” or “unknown.” If “known,” continue with question 26. If “unknown” or “not applicable,” continue with question 28. Report “not applicable” for recipients with non-secretory myeloma.

Question 26: Original monoclonal bands:

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

Question 27: New monoclonal (or oligoclonal) bands:

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

Questions 28-29: Total urine protein in 24 hours:

Indicate whether the amount of urinary protein at the time of best response was “known” or “unknown.” The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value and unit of measure in question 29. If “unknown” or “not applicable,” continue with question 30. Report “not

applicable" for recipients with non-secretory myeloma.

Questions 30-31: Urine albumin / creatinine ratio:

Indicate whether the urinary albumin / creatinine ratio was "known" or "unknown" at the time of best response. The value reported here should be based on a 24-hour urine collection. If "known," report the laboratory value and unit of measure documented on the laboratory report in question 31. If "unknown," continue with question 32. This question is only required if the primary disease (question 1) is MGRS or Amyloidosis or if there is evidence / history of (question 2) MGRS or Amyloidosis.

Questions 32-33: Urine protein / creatinine ratio:

Indicate whether the urinary protein / creatinine ratio was "known" or "unknown" at the time of best response. The value reported here should be based on a 24-hour urine collection. If "known," report the laboratory value and unit of measure documented on the laboratory report in question 33. If "unknown," continue with question 34. This question is only required if the primary disease (question 1) is MGRS or Amyloidosis or if there is evidence / history of (question 2) MGRS or Amyloidosis.

Question 34: Was minimal residual disease (MRD) assessed post-HCT / CT or post-infusion evaluation? (report only bone marrow or blood results):

Minimal residual disease (MRD), is an indicator of increased risk for disease relapse and / or progression. MRD can be assessed by different methods including, but not limited to, next generation sequencing (NGS), Sanger sequencing, polymerase chain reaction (PCR) testing, chromosomal / genomic microarray analysis, fluorescence in situ hybridization (FISH), karyotyping, or flow cytometry.

Indicate if MRD was performed by next generation sequencing (NGS) or next generation flow (NGF) at the time of best response.

If any MRD testing was performed for patients with myeloma, answer question 34 as "yes" and continue with question 35. If no MRD testing methods were performed, report "no" and continue with question 43.

Questions 35-36: Next generation sequencing (NGS):

Indicate whether the MRD result at the time of best response is "positive," "negative," or "not done" by NGS testing. If "positive," report the sample source (blood or bone marrow) in question 36 and continue with question 37. If "negative" or "not done," continue with question 39.

Questions 37-38 : Indicate the sensitivity of the next generation sequencing (NGS) testing:

Indicate the testing sensitivity of the NGS testing performed at the time of best response. If the specificity is not listed in this section, report "other" and specify the sensitivity as documented on the laboratory report in question 38.

Questions 39-40: Next generation flow (NGF):

Indicate whether the MRD result at the time of best response is “positive,” “negative,” or “not done” by NGF testing.

- If “positive,” report the sample source (blood or bone marrow) in question 40 and continue with question 43
- If “negative” report the sample source (blood or bone marrow) in question 40 and continue with question 41
- If “not done,” continue with question 43.

Questions 41-42: Indicate the sensitivity of the next generation flow (NGF) testing:

Indicate the testing sensitivity of the NGF testing performed at the time of best response.

NGF testing is used to identify minimal residual disease (MRD) in patients with multiple myeloma. Some NGF reports include a “level of detection” rather than a “level of sensitivity.” In these cases, the “level of sensitivity” can be derived from the level of detection. Please refer to the report and example below for further instruction.

	PERCENT	#/µL	
TOTAL CELLS	100.0	8,800	
% VIABLE	99.9	8,791	
TOTAL PLASMA CELLS	0.002		
NORMAL PLASMA CELLS			
% OF TOTAL CELLS	0.002	0.2	cells/µL
% OF PLASMA CELLS	96.200		
NUMBER OF NORMAL PLASMA CELLS	100		
ABNORMAL PLASMA CELLS			
% OF TOTAL CELLS	0.000	0.0	cells/µL
% OF PLASMA CELLS	3.800		
NUMBER OF ATYPICAL PLASMA CELLS	4	→	
LOWER LIMIT OF DETECTION (OF TOTAL CELLS)	0.001		
MAST	0.007		
HEMATOGONES	0.716		
ERYTHROBLASTS	2.945		

INTERPRETATION OF ATYPICAL PLASMA CELL NUMBER
NEGATIVE: LESS THAN 20 CELLS
EQUIVOCAL: 20 - 50 CELLS
POSITIVE: GREATER THAN 50 CELLS

Example:

- Level of Detection: 0.001 *is equal to:*
- Level of Sensitivity: 10^{-5} (1/100,000 cells) *and should be reported in question 41)*

If the specificity is not listed in this section, report “other” and specify the sensitivity as documented on the laboratory report in question 42.

Questions 43-44: Plasma cells in bone marrow aspirate by flow cytometry:

Indicate whether the percentage of plasma cells in the bone marrow aspirate assessed by flow cytometry at the time of best response is “known” or “unknown.” If “known,” report the percentage of plasma cells in the bone marrow aspirate documented on the pathology report in question 44. If “unknown,” continue with question 45.

Questions 45-46: Plasma cells in bone marrow aspirate by morphologic assessment:

Under normal circumstances, the marrow aspirate is used to obtain the differential cell count, review morphology of the cells, and 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 is possible that the plasma cell numbers may vary between the aspirate and biopsy. For this reason, this form captures the plasma cell percentage by both methods in questions 45-48.

- 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.

Indicate whether the percentage of plasma cells in the bone marrow aspirate was “known” or “unknown” by morphologic assessment at the time of best response. If “known,” report the percentage of plasma cells in the bone marrow aspirate documented on the pathology report in question 46. If “unknown,” continue with question 47.

Questions 47-48: Plasma cells in bone marrow biopsy:

Indicate whether the percentage of plasma cells in the bone marrow biopsy at the time of best response is “known” or “unknown.” If “known,” report the percentage of plasma cells in the bone marrow biopsy documented on the pathology report in question 48. If “unknown,” continue with question 49.

Question 49: Was a PET / CT scan performed?

A PET / CT combines the results of the PET (Positron Emission Tomography) scan along with the results of a CT (Computed Tomography) scan. If a PET / CT scan was performed at the time of best response, indicate “yes” and continue with question 50. If a PET / CT scan was not performed, select “no” and continue with question 54.

Questions 50-51: Was the PET / CT scan positive for myeloma involvement at any disease site?

Indicate if the PET / CT scan was positive for myeloma involvement at any disease site. If positive at any site, report “yes” for question 50 and specify which area(s) show involvement in question 51. If negative, report “no” and continue with question 52 .

Questions 52-53: Date of PET / CT scan:

Indicate if the date of the PET / CT scan was “known” or “unknown” at the time of best response. If “known,” report the assessment date in question 53. If “unknown,” continue with question 54.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q54-109: Organ Parameters of Amyloidosis at the Time of Best Response

! Complete questions 54-109 for amyloid patients only. If diagnosis was other than amyloidosis or there is no history of it, continue with question 110.

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 these questions is to determine the best overall response to HCT or cellular therapy, which could include any response to planned therapy post-HCT or post-cellular therapy, 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 or post-cellular therapy 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 54: 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,” and continue with question 88. If the recipient never had evidence of cardiac involvement in their disease, select “not applicable,” and continue with question 88.

Questions 55-56: 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 56. If the date is unknown, select “unknown” and continue with question 57. If the best response to transplant was already reported in a previous reporting period, select “previously reported” and continue with question 88.

Question 57: Was the left ventricular ejection fraction measured?

The left ventricular ejection fraction (LVEF) is a percentage that represents the volume of blood pumped from the left ventricle into the aorta (also known as stroke volume) compared to the volume of blood in the ventricle just prior to the heart contraction (also known as end diastolic volume). Indicate if the left ventricular ejection fraction (LVEF) was measured. If “yes,” continue with question 58. If “no,” continue with question 60.

Question 58: Specify the left ventricular ejection fraction:

Indicate the left ventricular ejection fraction at the time of best response. Most imaging reports will report the LVEF. If the LVEF is not explicitly documented it should be determined by dividing the stroke volume (SV, the volume of blood pumped into the aorta from the left ventricle) by the end diastolic volume (EDV, the volume of blood in the left ventricle just prior to contraction) of the left ventricle . For example, if the stroke volume was 75 ml and the end diastolic volume was 150ml, the ejection fraction would be 50%.

Question 59 : Specify the method used to determine the left ventricular ejection fraction:

Indicate the method used to determine the LVEF value.

Question 60: Was diastolic dysfunction present?

Diastole is the period in which chambers of the heart fill with blood. Diastolic dysfunction may be characterized by the difficulty of the ventricles to expand and contract appropriately due to stiffening of the heart walls by amyloid deposits. Indicate if diastolic dysfunction was present. Specify “yes,” “no,” or “unknown,” and continue with question 61.

Questions 61-62: Specify the intraventricular septal wall thickness measured by echocardiogram:

The heart is divided into the right and left sides by the septum. The area between the left and right ventricles is the intraventricular septum. Indicate if the intraventricular septal thickness was measured at the time of best response. If “yes,” report the value as documented on the echocardiogram in question 62. If “no,” or not measured by echocardiogram, continue with question 63.

Questions 63-64: Specify left ventricular (LV) strain percentage:

A strain pattern, as determined by electrocardiography, is a well-recognized marker of hypertrophy of the left ventricular (LVH) and is characterized by ST depression and T wave inversion on a resting ECG / EKG. The LV strain percentage is typically a negative percentage. The normal range for the LV global longitudinal strain (LV GLS) is -15.9% to -22.1%. Indicate if the left ventricular strain percentage was measured at the time of best response. If “yes,” based on evaluation by electrocardiogram, indicate the strain percentage in question 64. If “no,” or not measured by electrocardiogram, continue with question 65.

Questions 65-66: Were any serum cardiac biomarkers assessed?

Assessment of cardiac biomarkers helps determine if injury to cardiac tissue has occurred. Cardiac biomarkers include brain natriuretic peptide (BNP), N-terminal prohormone brain natriuretic peptide (NT-proBNP), troponin I, troponin T, and high-sensitivity troponin T. Indicate if serum cardiac biomarkers were assessed at the time of best response. If “yes,” report the date assessed in question 66 and continue with question 67. If “no” or “unknown,” continue with question 82.

Questions 67-68: Brain natriuretic peptide (BNP):

Indicate if the BNP was assessed at the time of best response. If “yes,” report the value (in pg/mL) in

question 68 and continue with question 69. If “no,” continue with question 70.

Question 69: Upper limit of normal for BNP:

Indicate the upper limit of normal for BNP (in pg/mL) found on the laboratory report.

Questions 70-71: N-terminal prohormone brain natriuretic peptide (NT-proBNP):

Indicate if the NT-proBNP was assessed at the time of best response. If “yes,” report the value (in pg/mL) in question 71 and continue with question 72. If “no,” continue with question 73.

Question 72: Upper limit of normal for NT-proBNP:

Indicate the upper limit of normal (in pg/mL) for NT-proBNP found on the laboratory report.

Questions 73-74: Troponin I:

Indicate if the Troponin I was assessed at the time of best response. If “yes,” report the value (in µg/L) in question 74 and continue with question 75. If “no,” continue with question 76.

Question 75: Upper limit of normal for troponin I:

Indicate the upper limit of normal (in µg/L) for Troponin I found on the laboratory report.

Questions 76-77: Troponin T:

Indicate if the Troponin T was assessed at the time of best response. If “yes,” report the value (in µg/L) in question 77 and continue with question 78. If “no,” continue with question 79.

Question 78: Upper limit of normal for Troponin T:

Indicate the upper limit of normal (in µg/L) for Troponin T found on the laboratory report.

Questions 79-80: High-sensitivity troponin T:

Indicate if the high-sensitivity troponin T was assessed at the time of best response. If “yes,” report the value (in ng/L) in question 80 and continue with question 81. If “no,” continue with question 82.

Question 81: Upper limit of normal for high-sensitivity troponin T:

Indicate the upper limit of normal (in ng/L) for high-sensitivity troponin T found on the laboratory report.

Questions 82-83: Was a 6-minute walk test performed?

A 6-minute walk test is used to assess total distance walked within 6 minutes to determine aerobic capacity and endurance. Indicate if a 6-minute walk test was performed at the time of best response. If “yes,” report the total distance walked and specify the unit of measure in question 83. If “no,” continue with question 84.

Question 84: Specify the recipient's New York Heart Association functional classification of heart failure: (Symptoms may include dyspnea, chest pain, fatigue, and palpitations; activity level should be assessed with consideration for patient's age group)

Indicate the recipient's New York Heart Association functional classification at the time of best response using the following guidelines:

- Class I – Able to perform ordinary activities without symptoms; no limitation of physical activity
- Class II – Ordinary physical activity produces symptoms; slight limitation of physical activity
- Class III – Less-than-ordinary physical activity produces symptoms; moderate limitation of physical activity
- Class IV – Symptoms present even at rest; severe limitation of physical activity

If the recipient's NYHA functional classification it not known, select "unknown."

Question 85: Recipient blood pressure:

Indicate if the recipient's blood pressure was assessed at the time of best response. If "known," continue with question 86. If "unknown," continue with question 88.

Questions 86-87: Recipient blood pressure results:

Report the recipient's blood pressure at the time of best response in question 86 and indicate in which body position the measurement was taken in question 87.

Question 88: Specify the recipient's best renal response:

Indicate the recipient's best renal response to HCT to date. See the Amyloidosis Response Criteria section 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 89-90: 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 90. If the date is unknown, select "unknown" and continue with question 91. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 91.

Question 91: 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," and

continue with question 98. If the recipient never had evidence of hepatic involvement in their disease, select "not applicable," and continue with question 98.

Questions 92-93: 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 93. If the date is unknown, select "unknown" and continue with question 94. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 94.

Question 94: Was hepatomegaly present on radiographic imaging (liver span > 15 cm) or on examination (liver edge palpable > 3 cm below right costal margin)?

At the time of best response, indicate if the liver spanned more than 15 cm (by radiographic imaging) or the edge of the liver was palpable more than 3 cm below the right costal margin (by physical examination). Indicate "yes" if hepatomegaly was present at the time of best response. Indicate "no" if hepatomegaly was not present at the time of best response. Indicate "unknown" if it was not possible to determine the presence or absence of hepatomegaly at the time of best response.

Questions 95-96: Specify the level of serum alkaline phosphatase:

Indicate whether the alkaline phosphatase (ALP) level at the time of best response is "known" or "unknown." If "known," report the laboratory count and unit of measure documented on the laboratory report in question 96 and continue with question 97. If "unknown," continue with question 98.

Question 97: Upper limit of normal for alkaline phosphatase:

Report the upper limit of normal for ALP from the laboratory report.

Question 98: Was there clinical improvement in GI involvement since the date of last report?

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 99. If "unknown" or "not applicable," continue with question 101. Report "not applicable" if the recipient never had evidence of GI involvement in their disease.

Questions 99-100: 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 100. If the date is unknown, select "unknown" and continue with question 101. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 101.

Question 101: Specify the recipient's best peripheral nervous system response:

Indicate the recipient's best peripheral nervous system 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" and continue with question 104. If the recipient never had evidence of disease-related peripheral neuropathy, select "not applicable" and continue with question 104.

Questions 102-103: 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 103. If the date is unknown, select "unknown" and continue with question 104. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 104.

Question 104: Did the recipient display any other clinical organ involvement?

Indicate if any other system was assessed for response to HCT. If the recipient had other site involvement reported in questions 116-118 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. If any other system was assessed, report "yes" and continue with question 105. If no other systems were assessed at the time of best response, report "no" and continue with question 110.

Questions 105-106: Specify the evidence of other organ involvement (check all that apply):

For each option, indicate if there was evidence of other organ involvement. Check all that apply. If there was other organ involvement not listed in this section, select "other organ involvement" in question 105 and specify the other organ in question 106.

Examples may include:

- Arthropathy is a disease of the joints. An example of a common arthropathy in patients with amyloidosis is carpal tunnel-like symptoms.
- Amyloid deposits may be found in the lung, impairing their function. Examples of lung involvement may be alveolar-septal disease, nodular disease, intra- and extra-thoracic adenopathy, pleural disease, and diaphragm deposition.
- Soft tissue involvement, other than those already listed, may include glandular involvement (such as submandibular glands).
- Any additional organ involvement, other than those already listed, may be reported in this section as "other organ involvement." The other organ involved will then be specified in question 106.

[5] Berk JL, O'Regan A, Skinner M. Pulmonary and tracheobronchial amyloidosis. Semin Respir Crit Care Med. 2002;23(2):155-65.

Question 107: Specify best response to HCT or cellular therapy for this system:

Indicate if the site's/system's best response to transplant was "improved response," "progression," or "no response/stable disease."

Questions 108-109: 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 109. If the date is unknown, select "unknown" and continue with question 110. If the best response to transplant was already reported in a previous reporting period, select "previously reported" and continue with question 110.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q110-141: POEMS Syndrome Assessment at the Time of Best Response

! Complete questions 110-141 for POEMS patients only. If POEMS was not reported as the primary disease for transplant (question 1) or as a preceding / concurrent disorder (question 2), skip to question 142.

The response time for POEMS 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 or cellular therapy, which could include any response to planned therapy post-HCT or post-cellular therapy, 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 or post-cellular therapy 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.

Questions 110-111: Specify POEMS clinical features at the time of best response (check all that apply):

Indicate which clinical features, **specific to POEMS only**, are present at the time of best response. Check all that apply. If there are other clinical features not listed in this section, select “other” in question 110, in addition to any available options that apply, and specify the other clinical feature in question 111.

Questions 112-113: Thyroid stimulating hormone (TSH):

Indicate whether the thyroid stimulating hormone (TSH) level was “known” or “unknown” at the time of best response. If “known,” report the value (in mU/L) in question 113 (mU/L is equivalent to µU/mL) and continue with question 114. If “unknown,” continue with question 115.

Question 114: Upper limit of normal for thyroid stimulating hormone (TSH) level:

Indicate the upper limit of normal (in mU/L) for thyroid stimulating hormone (TSH) level from the laboratory report.

Questions 115-116: Testosterone level:

Indicate whether the testosterone level was “known” or “unknown” at the time of best response. If “known,” report the value and unit of measure documented on the laboratory report in question 116 and continue with question 117. If “unknown,” continue with question 118.

Question 117: Upper limit of normal for testosterone level:

Indicate the upper limit of normal for testosterone level from the laboratory report.

Questions 118-119: Estradiol level:

Indicate whether the estradiol level was “known” or “unknown” at the time of best response. If “known,” report the value (in pg/mL) in question 119 and continue with question 120. If “unknown,” continue with question 121.

Question 120: Upper limit of normal for estradiol level:

Indicate the upper limit of normal (in pg/mL) for estradiol level found on the laboratory report.

Questions 121-122: Prolactin level:

Indicate whether the prolactin level was “known” or “unknown” at the time of best response. If “known,” report the value (in ng/mL) in question 122 and continue with question 123. If “unknown,” continue with question 124.

Question 123: Upper limit of normal for prolactin level:

Indicate the upper limit of normal (in ng/mL) for prolactin level found on the laboratory report.

Questions 124-125: Cortisol level:

Indicate whether the cortisol level was “known” or “unknown” at the time of best response. If “known,” report the value and unit of measure to the nearest tenth documented on the laboratory report in question 125 and continue with question 126. If “unknown,” continue with question 127.

Question 126: Upper limit of normal for cortisol level:

Indicate the upper limit of normal for cortisol level found on the laboratory report.

Questions 127-128: Interleukin-6:

Indicate whether the interleukin-6 value was “known” or “unknown” at the time of best response. If “known,” report the value (in pg/mL) to the nearest tenth in question 128 and continue with question 129. If “unknown,” continue with question 130.

Question 129: Upper limit of normal for interleukin-6:

Indicate the upper limit of normal for interleukin-6 found on the laboratory report.

Questions 130-131: Was pulmonary artery hypertension present?

Pulmonary hypertension (PH) refers to elevated pulmonary arterial pressure. PH can be due to primary elevation of pressure in the pulmonary arterial system alone (pulmonary arterial hypertension), or secondary to elevations of pressure in the pulmonary venous and pulmonary capillary systems (pulmonary venous hypertension; post-capillary PH). Indicate whether pulmonary artery hypertension was present at the time of best response. If present, select “yes” and report the estimated systolic artery pressure documented on the

laboratory report in question 131. If not present, report “no” and continue with question 132.

Questions 132-133: Forced vital capacity (FVC):

Forced vital capacity is the total amount of air that can be exhaled during the forced expiratory volume test. FVC is a measurement taken during spirometry studies. Indicate whether the forced vital capacity percentage was “known” or “unknown” at the time of best response. If “known,” report the percentage documented on the pulmonary function test (PFT) in question 133. If “unknown,” continue with question 134.

Questions 134-135: Total lung capacity:

Indicate whether the total lung volume was “known” or “unknown” at the time of best response. If “known,” report the value documented on the pulmonary function report in question 135. If “unknown,” continue with question 136.

Questions 136-137: Vascular endothelial growth factor (VEGF) serum value:

Vascular endothelial growth factor (VEGF) promotes the growth of new blood vessels and acts as a signaling protein influencing the rate at which this process is performed. Indicate whether the serum-derived vascular endothelial growth factor (VEGF) value was “known” or “unknown” at the time of best response. If “known,” report the value documented on the laboratory report in question 137 and continue with question 138. If “unknown,” continue with question 139.

Question 138: Upper limit of normal for vascular endothelial growth factor (VEGF) serum value:

Indicate the upper limit of normal for serum-derived vascular endothelial growth factor (VEGF) value found on the laboratory report.

Questions 139-140: Vascular endothelial growth factor (VEGF) plasma value:

Vascular endothelial growth factor (VEGF) promotes the growth of new blood vessels and acts as a signaling protein influencing the rate at which this process is performed. Indicate whether the plasma-derived vascular endothelial growth factor (VEGF) value was “known” or “unknown” at the time of best response. If “known,” report the value documented on the laboratory report in question 140 and continue with question 141. If “unknown,” continue with question 142.

Question 141: Upper limit of normal for vascular endothelial growth factor (VEGF) plasma value:

Indicate the upper limit of normal for plasma-derived vascular endothelial growth factor (VEGF) value found on the laboratory report.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q142-210: Post-Infusion Therapy

Question 142: Was therapy given since the date of last report for reasons other than relapse or progressive disease? (Include any maintenance and consolidation therapy prior to relapse as well as therapy given for persistent disease that has not progressed):

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 143. If “no” or “unknown,” continue with question 167.

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 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 lenalidomide therapy at 15 mg/day. The maintenance lenalidomide therapy can be reported in questions 142-166.

> **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 progressed and unplanned treatment is initiated. Only the maintenance lenalidomide would be reported in questions 142-166.

Question 143: 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 144. If “no,” continue with question 155.

Questions 144-145: 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 145. 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 146.

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 146-147: Date therapy stopped:

Indicate if the date the therapy stopped is “known”, “unknown,” or “not applicable.” 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 147. If “unknown,” continue with question148. Report “not applicable” if the recipient is still receiving therapy and continue with question 150.

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 the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Questions 148-149: Reason stopped:

Indicate the reason that this line of therapy stopped. If the reason the line of therapy was stopped is not listed in this section, select “other” and report the specific reason in question 149.

Questions 150-151: Was a standard drug regimen given?

Systemic chemotherapy / immunotherapy may involve administration of multiple drugs / agents during the line of therapy. Rather than reporting each drug separately, standard combination regimens should be reported using the options in question 151 when available. Review the regimen options provided in question 151. If the recipient’s line of therapy includes one of the regimens listed, report “yes” for question 150 and indicate the regimen that was given in question 151. If the recipient did not receive one of the standard regimens provided in question 151 as part of the line of therapy being reported, indicate “no” for question 150 and go to question 152.

Only one regimen may be reported for question 151. Generally, each regimen should be reported as a separate line of therapy. If the recipient received a regimen specified in question 151 as well as additional

systemic therapy drugs as part of the line of therapy being reported, indicate the standard regimen in question 151 and report the additional drugs in 152-154.

Questions 152-154: Were systemic drugs given?

Questions 152-154 are intended to capture systemic therapy drugs / agents not already reported in questions 150-151. If part or all of the recipient's regimen can be reported in questions 150-151, report them in those questions and do not report them again in questions 152-154. If all systemic therapy drugs given as part of the line of therapy being reported were included in the regimen indicated in question 151, report "no" for question 152 and go to question 155.

If the recipient received systemic chemotherapy drugs not already reported in questions 150-151 as part of the line of therapy being reported, report "yes" for question 152 and specify the chemotherapy drug(s) in questions 153-154. Otherwise, report "no" for question 152 and go to question 155.

If the center needs to report a systemic chemotherapy drug (or drugs) in question 153, but it is not listed as an option, report "other systemic therapy" and use question 154 to specify any drugs not already reported. Only report systemic chemotherapy drugs in questions 152-154.

Question 155: 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 or post-cellular therapy. If "yes," continue with question 156. If "no," continue with question 162.

Questions 156-157: Date therapy started:

Indicate if the date the radiation therapy started is "known" or "unknown." If "known," enter the date the line of radiation therapy began in question 157.

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 158-159: Date therapy stopped:

Indicate if the date the radiation therapy stopped is "known," "unknown," or "not applicable." If "known", enter the date the line of radiation therapy ended in question 159. Report "not applicable" if the recipient is still receiving therapy.

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 160-161: Dose of radiation therapy:

Indicate if the dose of radiation administered was “known” or “unknown.” If “known,” continue with question 161and indicate the total dose of radiation given. If radiation was given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was given in fractionated doses, multiply the total number of fractions by the dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy). If “unknown,” continue with question 162.

Example:
Radiation order: TBI, 200 cGy/day for three days (3 doses)
Total dose: 200 cGy x 3 doses = 600 cGy
Report “Dose of radiation therapy” as 600 cGy

Question 162: Cellular therapy (e.g., CAR-T cells):

Cellular therapy treatment strategies include isolation and transfer of specific stem cell populations, administration of effector cells (e.g., cytotoxic T-cells), induction of mature cells to become pluripotent cells, and reprogramming of mature cells (e.g., CAR-T cells).

Report “yes” if the recipient received cellular therapy as part of the line of therapy being reported. If not, report “no.” If “yes” was reported, a Pre-CTED (4000) Form should be completed for the cellular therapy infusion.

Question 163: Best hematologic response to line of therapy:

! This question will be answered for recipients whose primary disease for infusion includes all plasma cell disorders except amyloidosis. If amyloidosis was reported as the primary disease for infusion (question 1), skip questions 163-164 and continue with question 165.

POEMS Syndrome
If the recipient’s primary disease is POEMS Syndrome (without evidence of myeloma), go to question 169

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.

The percentage of plasma cells in the bone marrow aspirate may also be identified on a flow cytometry report. A flow cytometry result may be used to confirm CR (e.g., < 5% plasma cells in the bone marrow) as

long as the method was high sensitivity or next generation flow.

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

Question 164: Date assessed:

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. If recipient is still receiving treatment, the date assessed should be the date of best response within the current reporting period.

Question 165: Best hematologic response to line of therapy (for Amyloid patients only):

> ! Complete questions 165-166 for amyloidosis patients only. If amyloidosis was not reported as the primary disease for infusion (question 1) or as a preceding / concurrent disorder (question 2), skip to question 167.

Indicate the best response to the line of therapy. See the Amyloidosis Response Criteria section for disease status definitions.

Question 166: Date assessed:

Enter the date the best response was assessed. 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.

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

Copy questions 143-166 to report more than one line of therapy.

Question 167: Has the disease relapsed or progressed since the date of last report?

Indicate “yes” if a relapse or progression occurred since the date of the last report and continue with question 168. 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 experience a relapse or progression since the date of the last report and continue with question 169. If it is unknown if the recipient relapsed or progressed since the date of the last

report, report “unknown” and continue with question 169.

See Multiple Myeloma Response Criteria for progressive disease and Relapse from CR disease status definitions.

Question 168: Date of relapse/progression:

Enter the date the relapse or progression occurred during the reporting period. 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. Continue with question 169.

Question 169: Was treatment given for relapse or progression?

Indicate if the recipient received treatment post-infusion for relapsed or progressive disease since the date of last report. If “yes,” continue with question 170. If “no,” continue with question 190.

Question 170: 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 171. If “no,” continue with question 182.

Questions 171-172: 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 172. 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 173.

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 173-174: Date therapy stopped:

Indicate if the date the therapy stopped is “known,” “unknown,” or “not applicable.” 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 174. If “unknown,” continue with question 175. Report “not applicable” if the recipient is still receiving therapy and continue with question 177.

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 the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Questions 175-176: Reason therapy stopped:

Indicate the reason that this line of therapy stopped. If the reason the line of therapy was stopped is not listed in this section, select “other” and report the specific reason in question 176.

Questions 177-178: Was a standard drug regimen given?

Systemic chemotherapy / immunotherapy may involve administration of multiple drugs / agents during the line of therapy. Rather than reporting each drug separately, standard combination regimens should be reported using the options in question 178 when available. Review the regimen options provided in question 178. If the recipient’s line of therapy includes one of the regimens listed, report “yes” for question 177 and indicate the regimen that was given in question 178. If the recipient did not receive one of the standard regimens provided in question 178 as part of the line of therapy being reported, indicate “no” for question 177 and go to question 179.

Only one regimen may be reported for question 178. Generally, each regimen should be reported as a separate line of therapy. If the recipient received a regimen specified in question 178 as well as additional systemic therapy drugs as part of the line of therapy being reported, indicate the standard regimen in question 178 and report the additional drugs in 179-181.

Questions 179-181: Were systemic drugs given?

Questions 179-181 are intended to capture systemic therapy drugs / agents not already reported in questions 177-178. If part or all of the recipient’s regimen can be reported in questions 177-178, report them in those questions and do not report them again in questions 179-181. If all systemic therapy drugs given as part of the line of therapy being reported were included in the regimen indicated in question 178, report “no” for question 179 and go to question 182.

If the recipient received systemic chemotherapy drugs not already reported in questions 177-178 as part of the line of therapy being reported, report “yes” for question 179 and specify the chemotherapy drug(s) in questions 180-181. Otherwise, report “no” for question 179 and go to question 182.

If the center needs to report a systemic chemotherapy drug (or drugs) in question 180, but it is not listed as an option, report “other systemic therapy” and use question 181 to specify any drugs not already reported. Only report systemic chemotherapy drugs in questions 179-181.

Question 182: 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 or post-cellular therapy. If “yes,” continue with question 183. If “no,” continue with question 189.

Questions 183-184: Date therapy started:

Indicate if the date the radiation therapy started is “known” or “unknown.” If “known,” enter the date the line of radiation therapy began in question 184.

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 185-186: Date therapy stopped:

Indicate if the date the radiation therapy stopped is “known,” “unknown,” or “not applicable.” If “known”, enter the date the line of radiation therapy ended in question 186. Report “not applicable” if the recipient is still receiving therapy.

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 187-188: Dose of radiation therapy:

Indicate if the dose of radiation administered was “known” or “unknown.” If “known,” continue with question 188 and indicate the total dose of radiation given. If radiation was given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was given in fractionated doses, multiply the total number of fractions by the dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy). If “unknown,” continue with question 189.

Example:
Radiation order: TBI, 200 cGy/day for three days (3 doses)
Total dose: 200 cGy x 3 doses = 600 cGy
Report “Dose of radiation therapy” as 600 cGy

Question 189: Cellular therapy (e.g., CAR-T cells):

Cellular therapy treatment strategies include isolation and transfer of specific stem cell populations, administration of effector cells (e.g., cytotoxic T-cells), induction of mature cells to become pluripotent cells, and reprogramming of mature cells (e.g., CAR-T cells).

Report “yes” if the recipient received cellular therapy as part of the line of therapy being reported. If not, report “no.” If “yes” was reported, a Pre-CTED (4000) Form should be completed for the cellular therapy infusion.

Copy questions 170-189 to report more than one line of therapy.

Question 190: Was maintenance therapy given treatment relapse / progression since the date of last report?

Indicate if the recipient received maintenance therapy *after* treatment for relapse / progression since the date of last report. If “yes,” continue with question 191. If “no,” continue with question 211.

If it is not known or not possible to determine if the recipient was placed on subsequent maintenance therapy after treatment for relapse / progression, then select “Unknown” and proceed to question 211. This option should be used sparingly and only in cases when it is truly unknown as to whether maintenance therapy was given within the reporting period after treatment for relapse / progression.

Indicate “Not Applicable” if the recipient did not receive treatment for relapse / progression. Please see the example below:

Example: A recipient was in CR and was receiving maintenance Revlimid. Due to health issues, the maintenance therapy was briefly discontinued; however, the recipient’s IgG reappeared during this time. The patient was not treated for relapse and eventually continued on with the Revlimid maintenance. In this case, question 190 would be answered as “Not Applicable” because he was not treated for relapse but instead continued on with his maintenance therapy.

Question 191: 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 192. If “no,” continue with question 203.

Questions 192-193: 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 193. 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 194.

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 194-195: Date therapy stopped:

Indicate if the date the therapy stopped is “known,” “unknown,” or “not applicable.” 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 195. If “unknown,” continue with question 196. Report “not applicable” if the recipient is still receiving therapy and continue with question 198 .

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 the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Questions 196-197: Reason stopped:

Indicate the reason that this line of therapy stopped. If the reason the line of therapy was stopped is not listed in this section, select “other” and report the specific reason in question 197.

Questions 198-199: Was a standard drug regimen given?

Systemic chemotherapy / immunotherapy may involve administration of multiple drugs / agents during the line of therapy. Rather than reporting each drug separately, standard combination regimens should be reported using the options in question 199 when available. Review the regimen options provided in question 199. If the recipient’s line of therapy includes one of the regimens listed, report “yes” for question 198 and indicate the regimen that was given in question 199. If the recipient did not receive one of the standard regimens provided in question 199 as part of the line of therapy being reported, indicate “no” for question 198 and go to question 200.

Only one regimen may be reported for question 199. Generally, each regimen should be reported as a separate line of therapy. If the recipient received a regimen specified in question 199 as well as additional systemic therapy drugs as part of the line of therapy being reported, indicate the standard regimen in question 199 and report the additional drugs in 200-202.

Questions 200-202: Were systemic drugs given?

Questions 200-202 are intended to capture systemic therapy drugs / agents not already reported in questions 198-199. If part or all of the recipient’s regimen can be reported in questions 198-199, report them in those questions and do not report them again in questions 200-202. If all systemic therapy drugs given as part of the line of therapy being reported were included in the regimen indicated in question 199, report “no” for question 200 and go to question 203.

If the recipient received systemic chemotherapy drugs not already reported in questions 198-199 as part of the line of therapy being reported, report “yes” for question 200 and specify the chemotherapy drug(s) in questions 201-202. Otherwise, report “no” for question 200 and go to question 203.

If the center needs to report a systemic chemotherapy drug (or drugs) in question 201, but it is not listed as an option, report “other systemic therapy” and use question 202 to specify any drugs not already reported. Only report systemic chemotherapy drugs in questions 200-202.

Question 203: 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 or post-cellular therapy. If “yes,” continue with question 204. If “no,” continue with question

210.

Questions 204-205: 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 205.

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 206-207: Date therapy stopped:

Indicate if the date the therapy started is “known,” “unknown,” or “not applicable.” If “known”, enter the date the line of radiation therapy ended in question 207. Report “not applicable” if the recipient is still receiving therapy and continue with question 210.

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 208-209: Dose of radiation therapy:

Indicate if the dose of radiation administered was “known” or “unknown.” If “known,” continue with question 209 and indicate the total dose of radiation given. If radiation was given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was given in fractionated doses, multiply the total number of fractions by the dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy). If “unknown,” continue with question 210.

Example:
Radiation order: TBI, 200 cGy/day for three days (3 doses)
Total dose: 200 cGy x 3 doses = 600 cGy
Report “Dose of radiation therapy” as 600 cGy

Question 210: Cellular therapy (e.g., CAR-T cells):

Cellular therapy treatment strategies include isolation and transfer of specific stem cell populations, administration of effector cells (e.g., cytotoxic T-cells), induction of mature cells to become pluripotent cells, and reprogramming of mature cells (e.g., CAR-T cells).

Report “yes” if the recipient received cellular therapy as part of the line of therapy being reported. If not, report “no.” If “yes” was reported, a Pre-CTED (4000) Form should be completed for the cellular therapy infusion.

Copy questions 191-210 to report more than one line of therapy.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q211-252: Disease Status at the Time of Evaluation for this Reporting Period

For questions 211-252, report values obtained at the last evaluation for this reporting period. If testing is performed multiple times during the reporting period, report the values obtained at the last evaluation in the reporting period.

Questions 211-212: Serum creatinine:

Indicate whether the serum creatinine was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the laboratory value and unit of measure documented on the laboratory report in question 212 and continue with question 213. If “unknown,” continue with question 214.

Questions 213: Upper limit of serum creatinine:

Indicate the upper limit of normal for serum creatinine value found on the laboratory report.

Questions 214-215: Serum monoclonal protein (M-spike) (only from electrophoresis):

Monoclonal gammopathy is defined as the increased production of abnormal immunoglobulins. 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 215. If “unknown” or “not applicable,” continue with question 216. Report “not applicable” for recipients with non-secretory myeloma.

Do not report immunofixation results here.

Questions 216-217: Serum immunofixation:

Indicate whether the serum paraprotein was detected on serum immunofixation. If detected, report “known” in question 216 and indicate the M-spike type, including both the heavy and light chain distinctions, in question 217. The involved heavy chain and light chain can be identified but not quantified using this test. If multiple M-spike types are involved, select each that are present in question 217 (e.g. IgG Kappa and IgA Lambda). Report “no bands present” if serum immunofixation was performed but no paraprotein was identified.

If “unknown” or “not applicable,” continue with question 220. Report “not applicable” for recipients with non-secretory myeloma.

Question 218: Original monoclonal bands:

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

Question 219: New monoclonal (or oligoclonal) bands:

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

Questions 220-221: Serum free light chains – κ (kappa):

Indicate whether the serum κ (kappa) free light chain level at the time of evaluation for this reporting period is “known” or “unknown.” 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 221 and continue with question 222. If “unknown” or “not applicable,” continue with question 223. Report “not applicable” for recipients with non-secretory myeloma.

Question 222: 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 found on the laboratory report.

Questions 223-224: Serum free light chains – λ (lambda):

Indicate whether the serum λ (lambda) free light chain level at the time of evaluation for this reporting period is “known” or “unknown.” This value should reflect the quantity of serum free light chains, not a quantification of total light chains. If “known,” use question 224 to record the value and unit of measure documented on the laboratory report and continue with question 225. If “unknown” or “not applicable,” continue with question 226. Report “not applicable” for recipients with non-secretory myeloma.

Question 225: Upper limit of normal for λ free light chains:

Indicate the upper limit of normal for λ (lambda) free light chains value and the unit of measure found on the laboratory report.

Questions 226-227: Total urine protein in 24 hours:

Indicate whether the amount of urinary protein at the time of evaluation for this reporting period was “known” or “unknown.” The value reported here should be based on a 24-hour urine collection. If “known,” report the laboratory value and unit of measure documented on the laboratory report in question 227. If “unknown” or “not applicable,” continue with question 228. Report “not applicable” for recipients with non-secretory myeloma.

Questions 228-229: Urine albumin / creatinine ratio:

Indicate whether the urinary albumin / creatinine ratio 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 and unit of measure documented on the laboratory report in question 229. If “unknown,” continue with question 230.

Questions 230-231: Urine protein / creatinine ratio:

Indicate whether the urinary protein / creatinine ratio 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 and unit of measure documented on the laboratory report in question 231. If “unknown,” continue with question 232.

Questions 232-233: Urinary monoclonal protein (M-spike):

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 and unit of measure documented on the laboratory report in question 233. If “unknown” or “not applicable,” continue with question 234. Report “not applicable” for recipients with non-secretory myeloma.

Question 234: 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 at the time of evaluation for this reporting period is “known” or “unknown.” If “known,” continue with question 235. If “unknown” or “not applicable,” continue with question 237. Report “not applicable” for recipients with non-secretory myeloma.

Question 235: Original monoclonal bands:

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

Question 236: New monoclonal (or oligoclonal) bands:

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

Questions 237-238: Plasma cells in bone marrow aspirate by flow cytometry:

Indicate whether the percentage of plasma cells in the bone marrow aspirate assessed by flow cytometry at the time of evaluation for this reporting period is “known” or “unknown.” If “known,” report the percentage of plasma cells in the bone marrow aspirate documented on the pathology report in question 238. If “unknown,” continue with question 239.

Questions 239-240: Plasma cells in bone marrow aspirate by morphologic assessment:

Under normal circumstances, the marrow aspirate is used to obtain the differential cell count, review morphology of the cells, and 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 is possible that the plasma cell numbers may vary between the aspirate and biopsy. For this reason, this form captures the

plasma cell percentage by both methods in questions 239-242.

- 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.

Indicate whether the percentage of plasma cells in the bone marrow aspirate was “known” or “unknown” by morphologic assessment at the time of evaluation for this reporting period. If “known,” report the percentage of plasma cells in the bone marrow aspirate documented on the pathology report in question 240. If “unknown,” continue with question 241.

Questions 241-242: Plasma cells in bone marrow biopsy:

Indicate whether the percentage of plasma cells in the bone marrow biopsy at the time of evaluation for this reporting period is “known” or “unknown.” If “known,” report the percentage of plasma cells in the bone marrow biopsy documented on the pathology report in question 242. If “unknown,” continue with question 243.

Question 243: Did the recipient receive dialysis?

Indicate if the recipient received dialysis during this reporting period. If the recipient received dialysis at any point, report “yes” and continue with question 244. If the recipient did not receive dialysis during the reporting period, report “no” and continue with question 246.

Questions 244-245: Date of dialysis:

Indicate if the date the recipient started dialysis was “known” or “unknown.” If “known,” report the date that dialysis began in question 245. If “unknown,” continue with question 246.

Question 246: Was a PET / CT scan performed?

A PET / CT combines the results of the PET (Positron Emission Tomography) scan along with the results of a CT (Computed Tomography) scan. If a PET / CT scan was performed at the time of evaluation for this reporting period, indicate “yes” and continue with question 247. If a PET / CT scan was not performed, select “no” and continue with question 251.

Questions 247-248: Was the PET / CT scan positive for myeloma involvement at any disease site?

Indicate if the PET / CT scan was positive for myeloma involvement at any disease site. If positive at any site, report “yes” for question 247 and specify which area(s) show involvement in question 248 and continue

with question 249. If negative, report “no” and continue with question 251.

Questions 249-250: Date of PET / CT scan:

Indicate if the date of the PET / CT scan was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the assessment date in question 250. If “unknown,” continue with question 251.

Question 251: What is the hematologic disease status at the time of the most current evaluation?

> ! This question will be answered for recipients whose primary disease for infusion includes all plasma cell disorders **except** amyloidosis. If amyloidosis was reported as the primary disease for infusion (question 1), skip questions 251-252 and continue with question 253.

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.

If the disease response prior to transplant is unknown, select “unknown” and continue with question 253.

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.

This question will not be enabled if the primary disease for transplant is monoclonal gammopathy of renal significance (MGRS).

Question 252: 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.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q253-311: Current Status of Amyloidosis for this Reporting Period

Complete questions 253-311 for amyloidosis patients only. If amyloidosis was not reported as the primary disease for infusion (question 1) or as a preceding / concurrent disorder (question 2), skip to question 312.

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.

Question 253: Specify the recipient's current hematologic status:

Indicate the recipient's current hematologic status at the time of evaluation for this reporting period. See the Amyloidosis Response Criteria section for disease status definitions.

The percentage of plasma cells in the bone marrow aspirate may also be identified on a flow cytometry report. A flow cytometry report may be used to confirm CR (e.g., < 5% plasma cells in the bone marrow) as long as the method was high sensitivity or next generation flow.

If the disease response prior to transplant is unknown, select "unknown" and continue with question 256.

Questions 254-255: Date assessed:

Indicate if the assessment date that reflects the recipient's current hematologic status was "known" or "unknown." If "known," continue with question 255 and 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 "unknown," continue with question 256.

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 256: Specify the recipient's current cardiac response:

Indicate the recipient's current cardiac status at the time of evaluation for this reporting period. See the Amyloidosis Response Criteria section for disease status definitions.

If the recipient's cardiac status was not assessed during the reporting period, select "not assessed" and continue with question 290. If the recipient never had evidence of cardiac involvement in their disease, select "not applicable" and continue with question 290.

Questions 257-258: Date assessed:

Indicate if the date of current cardiac assessment is "known" or "unknown." If the date of assessment for cardiac status is known, report the date in question 258. If the date is unknown, select "unknown" and continue with question 259.

Question 259: Was the left ventricular ejection fraction measured?

The left ventricular ejection fraction (LVEF) is a percentage that represents the volume of blood pumped from the left ventricle into the aorta (also known as stroke volume) compared to the volume of blood in the ventricle just prior to the heart contraction (also known as end diastolic volume). Indicate if the left ventricular ejection fraction (LVEF) was measured. If "yes," continue with question 260. If "no," continue with question 262.

Question 260: Specify the left ventricular ejection fraction:

Indicate the left ventricular ejection fraction at the time of evaluation for this reporting period. Most imaging reports will report the LVEF. If the LVEF is not explicitly documented it should be determined by dividing the stroke volume (SV, the volume of blood pumped into the aorta from the left ventricle) by the end diastolic volume (EDV, the volume of blood in the left ventricle just prior to contraction) of the left ventricle. For example, if the stroke volume was 75 ml and the end diastolic volume was 150ml, the ejection fraction would be 50%.

Question 261 : Specify the method used to determine the left ventricular ejection fraction:

Indicate the method used to determine the LVEF value.

Question 262: Was diastolic dysfunction present?

Diastole is the period in which chambers of the heart fill with blood. Diastolic dysfunction may be characterized by the difficulty of the ventricles to expand and contract appropriately due to stiffening of the heart walls by amyloid deposits. Indicate if diastolic dysfunction was present. Specify "yes," "no," or "unknown," and continue with question 263.

Questions 263-264: Specify the intraventricular septal wall thickness measured by echocardiogram:

The heart is divided into the right and left sides by the septum. The area between the left and right ventricles is the intraventricular septum. Indicate if the intraventricular septal thickness is "known" or "unknown." If "known," based on evaluation by echocardiogram, indicate the thickness of the intraventricular septal wall in question 264. If "unknown," or not measured by echocardiogram, continue with question 265.

Questions 265-266: Specify left ventricular (LV) strain percentage:

A strain pattern, as determined by electrocardiography, is a well-recognized marker of hypertrophy of the left ventricular (LVH) and is characterized by ST depression and T wave inversion on a resting ECG / EKG. The LV strain percentage is typically a negative percentage. The normal range for the LV global longitudinal strain (LV GLS) is -15.9% to -22.1%. Indicate if the left ventricular strain percentage is “known” or “unknown.” If “known,” based on evaluation by electrocardiogram, indicate the strain percentage in question 266. If “unknown,” or not measured by electrocardiogram, continue with question 267.

Questions 267-268: Were any serum cardiac biomarkers assessed?

Assessment of cardiac biomarkers helps determine if injury to cardiac tissue has occurred. Cardiac biomarkers include brain natriuretic peptide (BNP), N-terminal prohormone brain natriuretic peptide (NT-proBNP), troponin I, troponin T, and high-sensitivity troponin T. Indicate if serum cardiac biomarkers were assessed at the last evaluation. If “yes,” report the date assessed in question 268 and continue with question 269. If “no” or “unknown,” continue with question 284.

Questions 269-270: Brain natriuretic peptide (BNP):

Indicate if the BNP was assessed at the last evaluation. If “yes,” report the value (in pg/mL) in question 270 and continue with question 271. If “no,” continue with question 272.

Question 271: Upper limit of normal for BNP:

Indicate the upper limit of normal for BNP (in pg/mL) found on the laboratory report.

Questions 272-273: N-terminal prohormone brain natriuretic peptide (NT-proBNP):

Indicate if the NT-proBNP was assessed at the late evaluation. If “yes,” report the value (in pg/mL) in question 273 and continue with question 274. If “no,” continue with question 275.

Question 274: Upper limit of normal for NT-proBNP:

Indicate the upper limit of normal (in pg/mL) for NT-proBNP found on the laboratory report.

Questions 275-276: Troponin I:

Indicate if the Troponin I was assessed at the last evaluation. If “yes,” report the value (in µg/L) in question 276 and continue with question 277. If “no,” continue with question 278.

Question 277: Upper limit of normal for troponin I:

Indicate the upper limit of normal (in µg/L) for Troponin I found on the laboratory report.

Questions 278-279: Troponin T:

Indicate if the Troponin T was assessed at the last evaluation. If “yes,” report the value (in µg/L) in question

279 and continue with question 280. If “no,” continue with question 281.

Question 280: Upper limit of normal for Troponin T:

Indicate the upper limit of normal (in µg/L) for Troponin T found on the laboratory report.

Questions 281-282: High-sensitivity troponin T:

Indicate if the high-sensitivity troponin T was assessed at the last evaluation. If “yes,” report the value (in ng/L) in question 282 and continue with question 283. If “no,” continue with question 284.

Question 283: Upper limit of normal for high-sensitivity troponin T:

Indicate the upper limit of normal (in ng/L) for high-sensitivity troponin T found on the laboratory report.

Questions 284-285: Was a 6-minute walk test performed?

A 6-minute walk test is used to assess total distance walked within 6 minutes to determine aerobic capacity and endurance. Indicate if a 6-minute walk test was performed at the last evaluation. If “yes,” report the total distance walked and specify the unit of measure in question 285. If “no,” continue with question 286.

Question 286: Specify the recipient’s New York Heart Association functional classification of heart failure: (Symptoms may include dyspnea, chest pain, fatigue, and palpitations; activity level should be assessed with consideration for patient’s age group)

Indicate the recipient’s New York Heart Association functional classification at the last evaluation using the following guidelines:

- Class I – Able to perform ordinary activities without symptoms; no limitation of physical activity
- Class II – Ordinary physical activity produces symptoms; slight limitation of physical activity
- Class III – Less-than-ordinary physical activity produces symptoms; moderate limitation of physical activity
- Class IV – Symptoms present even at rest; severe limitation of physical activity

If the recipient’s NYHA functional classification it not known, select “unknown,” and continue with question 287.

Question 287: Recipient blood pressure:

Indicate if the recipient’s blood pressure was assessed at the last evaluation. If “known,” continue with question 288. If “unknown,” continue with question 290.

Questions 288-289: Recipient blood pressure results:

Report the recipient’s blood pressure at the last evaluation in question 288 and indicate in which body position the measurement was taken in question 289.

Question 290: Specify the recipient's current renal response:

Indicate the recipient's best renal response to HCT to date. See the Amyloidosis Response Criteria section for disease status definitions.

If the recipient's renal status was not assessed during the reporting period, select "not assessed" and continue with question 293.If the recipient never had evidence of renal involvement in their disease, select "not applicable" and continue with question 293.

Questions 291-292: Date assessed:

Indicate if the date the current renal response to transplant was assessed is "known," or "unknown." If the date of current renal response is known, report the date in question 292. If the date is unknown, select "unknown" and continue with question 293.

Question 293: Specify the recipient's current hepatic response:

Indicate the recipient's best hepatic response to HCT to date. See the Amyloidosis Response Criteria section for disease status definitions.

If the recipient's hepatic status was not assessed during the reporting period, select "not assessed" and continue with question 300. If the recipient never had evidence of hepatic involvement in their disease, select "not applicable" and continue with question 300.

Questions 294-295: Date assessed:

Indicate if the date the current hepatic response was assessed is "known," or "unknown." If the date of current hepatic response is known, report the date in question 295. If the date is unknown, select "unknown" and continue with question 296.

Question 296: Was hepatomegaly present on radiographic imaging (liver span > 15 cm) or on examination (liver edge palpable > 3 cm below right costal margin)?

At the last evaluation, indicate if the liver spanned more than 15 cm (by radiographic imaging) or the edge of the liver was palpable more than 3 cm below the right costal margin (by physical examination). Indicate "yes" if hepatomegaly was present at the last evaluation. Indicate "no" if hepatomegaly was not present at the last evaluation. Indicate "unknown" if it was not possible to determine the presence or absence of hepatomegaly at the last evaluation.

Questions 297-298: Specify the level of serum alkaline phosphatase:

Indicate whether the alkaline phosphatase (ALP) level at the time of evaluation for this reporting period is "known" or "unknown." If "known," report the laboratory count and unit of measure documented on the laboratory report in question 298 and continue with question 299. If "unknown," continue with question 300.

Question 299: Upper limit of normal for alkaline phosphatase:

Report the upper limit of normal for ALP found on the laboratory report.

Question 300: Was there clinical improvement in GI involvement since the date of last report?

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 301. If “unknown” or “not applicable,” continue with question 303. Report “not applicable” if the recipient never had evidence of GI involvement in their disease and continue with question 300.

Questions 301-302: 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 302. If the date is unknown, select “unknown” and continue with question 303. If the best response to transplant was already reported in a previous reporting period, select “previously reported” and continue with question 303.

Question 303: Specify the recipient’s current peripheral nervous system response:

Indicate the recipient’s best peripheral nervous system response to HCT to date. See the Amyloidosis Response Criteria section for disease status definitions.

If the recipient’s peripheral neuropathy was not assessed during the reporting period, select “not assessed” and continue with question 306. If the recipient never had evidence of disease-related peripheral neuropathy, select “not applicable” and continue with question 306.

Questions 304-305: Date assessed:

Indicate if the date the current peripheral neuropathy response to transplant was assessed is “known,” or “unknown.” If the date of current peripheral neuropathy response is “known,” report the date in question 305. If the date is unknown, select “unknown” and continue with question 306.

Question 306: Did the recipient display any other clinical organ involvement?

Indicate if any other system was assessed for response to HCT. If the recipient had other site involvement reported in questions 116-118 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. If any other system was assessed, report “yes” and continue with question 307. If no other systems were assessed at the time of best response, report “no” and continue with question 312.

Questions 307-308: Specify the evidence of other organ involvement (check all that apply):

For each option, indicate if there was evidence of other organ involvement at the last evaluation. Check all that apply. If there was other organ involvement not listed in this section, select “other organ involvement” in question 307 and specify the other organ in question 308.

Examples may include:

- Arthropathy is a disease of the joints. An example of a common arthropathy in patients with amyloidosis is carpal tunnel-like symptoms.
- Amyloid deposits may be found in the lung, impairing their function. Examples of lung involvement may be alveolar-septal disease, nodular disease, intra- and extra-thoracic adenopathy, pleural disease, and diaphragm deposition.[5]
- Soft tissue involvement, other than those already listed, may include glandular involvement (such as submandibular glands).
- Any additional organ involvement, other than those already listed, may be reported in this section as "other organ involvement." The other organ involved will then be specified in question 308.

[5] Berk JL, O'Regan A, Skinner M. Pulmonary and tracheobronchial amyloidosis. Semin Respir Crit Care Med. 2002;23(2):155-65.

Question 309: Specify the current status of this system:

Indicate if the site's/system's current status to transplant was "improved response," "progression," or "no response / stable disease."

Questions 310-311: Date assessed:

Indicate if the date the other site's/system's current status was assessed is "known," or "unknown." If the other site's/system's response is "known," report the date in question 311. If the date is unknown, select "unknown" and continue with question 312.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q312 – 343: Current Status of POEMS Syndrome for This Reporting Period

> ! Complete questions 312-343 for POEMS patients only. If POEMS was not reported as the primary disease for transplant (question 1) or as a preceding / concurrent disorder (question 2), submit the form.

Questions 312-313: Specify POEMS clinical features (check all that apply):

Indicate which clinical features, specific to POEMS only, are present at the time of evaluation for this reporting period. Check all that apply. If there are other clinical features not listed in this section, select “other” in question 312, in addition to any available options that apply, and specify the other clinical feature in question 313.

Questions 314-315: Thyroid stimulating hormone (TSH):

Indicate whether the thyroid stimulating hormone (TSH) level was “known” or “unknown” at the last evaluation. If “known,” report the value (in mU/L) in question 315 (mU/L is equivalent to µU/mL) and continue with question 316. If “unknown,” continue with question 317.

Question 316: Upper limit of normal for thyroid stimulating hormone (TSH) level:

Indicate the upper limit of normal (in mU/L) for thyroid stimulating hormone (TSH) level found on the laboratory report.

Questions 317-318: Testosterone level:

Indicate whether the testosterone level was “known” or “unknown” at the last evaluation. If “known,” report the value and unit of measure documented on the laboratory report in question 318 and continue with question 319. If “unknown,” continue with question 320.

Question 319: Upper limit of normal for testosterone level:

Indicate the upper limit of normal for testosterone level found on the laboratory report.

Questions 320-321: Estradiol level:

Indicate whether the estradiol level was “known” or “unknown” at the last evaluation. If “known,” report the value (in pg/mL) in question 321 and continue with question 322. If “unknown,” continue with question 323.

Question 322: Upper limit of normal for estradiol level:

Indicate the upper limit of normal (in pg/mL) for estradiol level found on the laboratory report.

Questions 323-324: Prolactin level:

Indicate whether the prolactin level was “known” or “unknown” at the last evaluation. If “known,” report the value (in ng/mL) in question 324 and continue with question 325. If “unknown,” continue with question 326.

Question 325: Upper limit of normal for prolactin level:

Indicate the upper limit of normal (in ng/mL) for prolactin level found on the laboratory report.

Questions 326-327: Cortisol level:

Indicate whether the cortisol level was “known” or “unknown” at the last evaluation. If “known,” report the value and unit of measure to the nearest tenth documented on the laboratory report in question 327 and continue with question 328. If “unknown,” continue with question 329.

Question 328: Upper limit of normal for cortisol level:

Indicate the upper limit of normal for cortisol level found on the laboratory report.

Questions 329-330: Interleukin-6:

Indicate whether the interleukin-6 value was “known” or “unknown” at the last evaluation. If “known,” report the value (in pg/mL) to the nearest tenth in question 330 and continue with question 331. If “unknown,” continue with question 332.

Question 331: Upper limit of normal for interleukin-6:

Indicate the upper limit of normal for interleukin-6 found on the laboratory report.

Questions 332-333: Was pulmonary artery hypertension present?

Pulmonary hypertension (PH) refers to elevated pulmonary arterial pressure. PH can be due to primary elevation of pressure in the pulmonary arterial system alone (pulmonary arterial hypertension), or secondary to elevations of pressure in the pulmonary venous and pulmonary capillary systems (pulmonary venous hypertension; post-capillary PH). Indicate whether pulmonary artery hypertension was present at the time of evaluation for this reporting period. If present, report the estimated systolic artery pressure documented on the laboratory report in question 333. If not present, continue with question 334.

Questions 334-335: Forced vital capacity (FVC):

Forced vital capacity is the total amount of air that can be exhaled during the forced expiratory volume test. FVC is a measurement taken during spirometry studies. Indicate whether the forced vital capacity percentage was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the percentage documented on the pulmonary function test (PFT) in question 335. If “unknown,” continue with question 336.

Questions 336-337: Total lung capacity:

Indicate whether the total lung capacity (volume) was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the value documented on the pulmonary function report in question 337. If “unknown,” continue with question 338.

Questions 338-339: Vascular endothelial growth factor (VEGF) serum value:

Vascular endothelial growth factor (VEGF) promotes the growth of new blood vessels and acts as a signaling protein influencing the rate at which this process is performed. Indicate whether the serum-derived vascular endothelial growth factor (VEGF) value was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the value documented on the laboratory report in question 339 and continue with question 340. If “unknown,” continue with question 341.

Question 340: Upper limit of normal for vascular endothelial growth factor (VEGF) serum value:

Indicate the upper limit of normal for serum-derived vascular endothelial growth factor (VEGF) value used found on the laboratory report.

Questions 341-342: Vascular endothelial growth factor (VEGF) plasma value:

Vascular endothelial growth factor (VEGF) promotes the growth of new blood vessels and acts as a signaling protein influencing the rate at which this process is performed. Indicate whether the plasma-derived vascular endothelial growth factor (VEGF) value was “known” or “unknown” at the time of evaluation for this reporting period. If “known,” report the value documented on the laboratory report in question 342 and continue with question 343. If “unknown,” submit the form.

Question 343: Upper limit of normal for vascular endothelial growth factor (VEGF) plasma value:

Indicate the upper limit of normal for plasma-derived vascular endothelial growth factor (VEGF) value found on the laboratory report.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020