

**INSERT VII**  
**Multiple Myeloma/Plasma Cell Leukemia**

**FOR REGISTRY USE ONLY:**  
I.D. **P** -     -        
Date received: \_\_\_\_\_

TEAM:     IUBMID:        
*(Institutional Unique Blood or Marrow Transplant Identification Number)*

Registry (circle one): **IBMTR** ABMTR

Date of transplant for which this form is being completed:        
Month Day Year

Date of report:        
Month Day Year

**Pretransplant Information\***

\* If this is a report of a second (or subsequent) transplant, check here  and go to Q.206

1. Date of diagnosis of multiple myeloma:        
Month Day Year

2. Prior solitary extramedullary plasmacytoma (in absence of bone marrow findings diagnostic for multiple myeloma or plasma cell leukemia)?

- 1  Yes  
0  No  
8  Unknown

3. Date of diagnosis:        
Month Day Year

3.<sup>2</sup> Plasma cell leukemia at diagnosis (blood plasma cells >20% of WBC differential or absolute blood plasma cells >2.0x10<sup>9</sup>/L [x10<sup>3</sup>/mm<sup>3</sup>])?

- 1  Yes  
0  No  
8  Unknown

3.<sup>3</sup> Date of diagnosis:        
Month Day Year

3.<sup>4</sup> Prior monoclonal gammopathy of unknown significance (MGUS)?

- 1  Yes  
0  No  
8  Unknown

3.<sup>5</sup> Date of diagnosis:        
Month Day Year

4. Immunochemical type:

- 0  Non-secretory  
1  Secretory  
8  Unknown

Note: If 2 paraproteins present, copy this page and describe each in Q.5-12

5. **Serum** heavy chain present?

- 1  Yes  
0  No  
8  Unknown

Specify: 4. Serum heavy chain type:

- 1  IgG 4  IgE  
2  IgA 5  IgM  
3  IgD 8  Unknown type

7. **Serum** light chain present?

- 1  Yes  
0  No  
8  Unknown

Specify: 8. Serum light chain type:

- 1  Kappa  
2  Lambda  
8  Unknown type

9. **Heavy chain** detected in **urine**?

- 1  Yes  
0  No  
8  Unknown

Specify: 10. Urine heavy chain type:

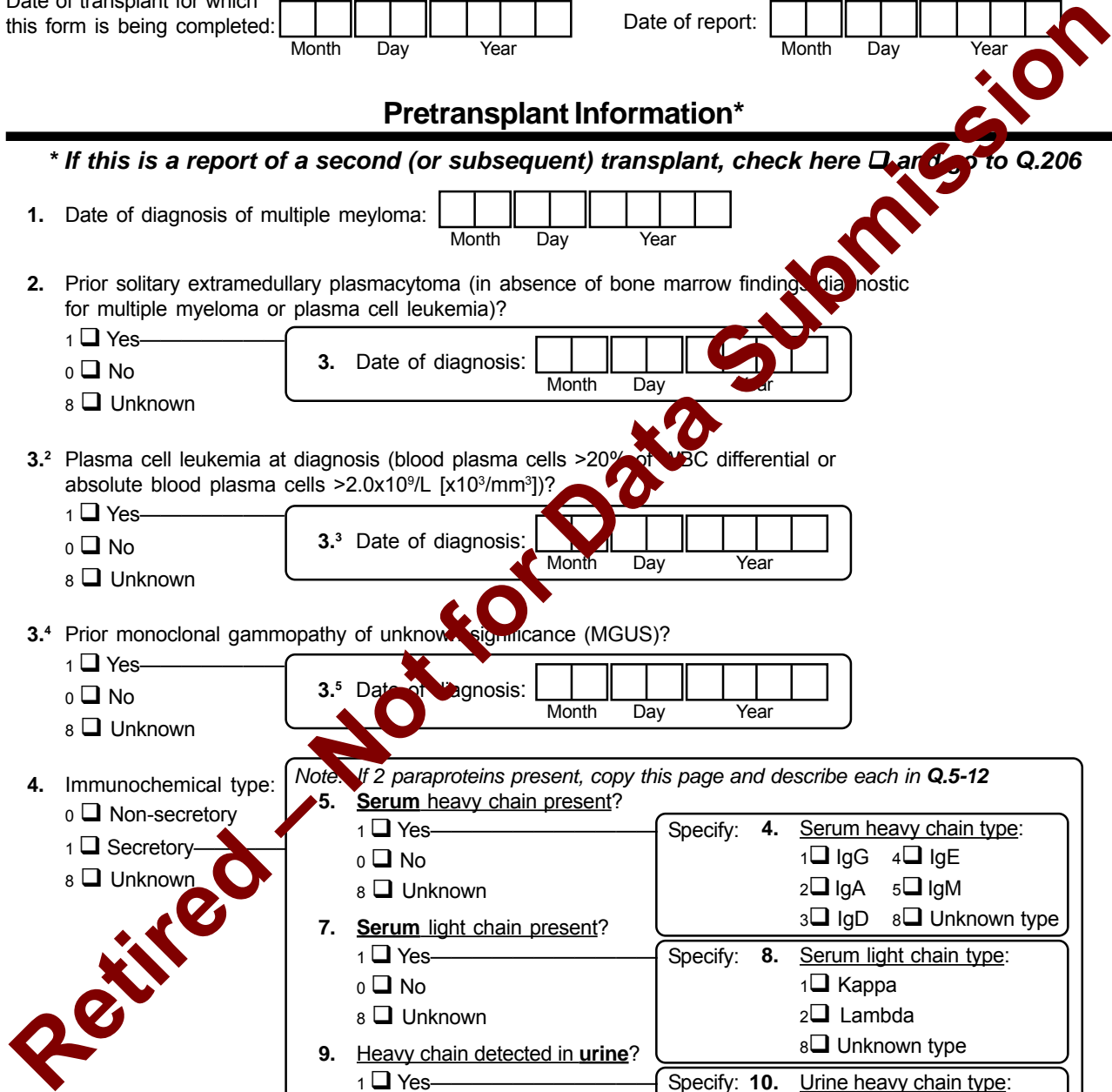
- 1  IgG 4  IgE  
2  IgA 5  IgM  
3  IgD 8  Unknown type

11. **Light chain** detected in **urine**?

- 1  Yes  
0  No  
8  Unknown

Specify: 12. Urine light chain type:

- 1  Kappa  
2  Lambda  
8  Unknown type



TEAM:

IUBMID:

**Clinical and Laboratory Findings Before First Treatment of Multiple Myeloma or Plasma Cell Leukemia**

14. Durie-Salmon stage of multiple myeloma or plasma cell leukemia at time of diagnosis:

1  Stage I

All of the following must be present:

- Hemoglobin >10 g/dL
- Serum calcium <12 mg/dL
- Normal bones on radiograph, or solitary plasmacytoma
- IgG <5 g/dL
- IgA <3 g/dL
- Urine light chains <4 g/24 hours

2  Stage II

Fitting neither Stage I nor III

3  Stage III

One of the following must be present:

- Hemoglobin <8.5 g/dL
- Serum calcium >12 mg/dL
- Advanced lytic bone lesions (>3 lytic lesions)
- IgG >7 g/dL
- IgA >5 g/dL
- Urine light chains >12 g/24 hours

8  Unknown

16. Were lytic bone lesions present?

1  Yes

0  No

8  Unknown

**Retired – Not for Data Submission**

TEAM:

IUBMID:

### Laboratory Values Before First Treatment of Multiple Myeloma or Plasma Cell Leukemia

- |  |                            | Specify Units   | Unknown                    |
|--|----------------------------|---|----------------------------|
| 28. Hemoglobin:                                      | <input type="text"/>       | 1 <input type="checkbox"/> g/dl 2 <input type="checkbox"/> g/L 3 <input type="checkbox"/> mmol/L <input type="checkbox"/> Transfused  | 8 <input type="checkbox"/> |
| 29. WBC:   | <input type="text"/>       | 1 <input type="checkbox"/> x 10 <sup>9</sup> /L (x 10 <sup>3</sup> /mm <sup>3</sup> ) 2 <input type="checkbox"/> x 10 <sup>6</sup> /L | 8 <input type="checkbox"/> |
| 30. Platelets:                                       | <input type="text"/>       | 1 <input type="checkbox"/> x 10 <sup>9</sup> /L (x 10 <sup>3</sup> /mm <sup>3</sup> ) 2 <input type="checkbox"/> x 10 <sup>6</sup> /L | 8 <input type="checkbox"/> |
| 32. Plasma cells in bone marrow (Aspirate):          | <input type="text"/> %     |   |                            |
| 34. Plasma cells in bone marrow (Biopsy):            | <input type="text"/> %     |   |                            |
| 35. Serum calcium:                                   | <input type="text"/>       | 1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> mmol/L 3 <input type="checkbox"/> mEq/L                                   | 8 <input type="checkbox"/> |
| 36. Serum albumin:                                   | <input type="text"/>       | 1 <input type="checkbox"/> g/dl 2 <input type="checkbox"/> g/L  | 8 <input type="checkbox"/> |
| 38. Serum creatinine:                                | <input type="text"/>       | 1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> mmol/L 3 <input type="checkbox"/> μmol/L                                  | 8 <input type="checkbox"/> |
| 39. Serum monoclonal Ig (only from electrophoresis): | <input type="text"/>       | 1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dl 3 <input type="checkbox"/> g/L                                       | 8 <input type="checkbox"/> |
| 40. Urinary monoclonal light chains:                 | <input type="text"/> g/24h |   | 8 <input type="checkbox"/> |
| 41. Serum β <sub>2</sub> -microglobulin:             | <input type="text"/>       | 1 <input type="checkbox"/> μg/dl 2 <input type="checkbox"/> mg/L 3 <input type="checkbox"/> nmol/L                                    | 8 <input type="checkbox"/> |
| 42. C-reactive protein:                              | <input type="text"/>       | 1 <input type="checkbox"/> mg/dl 2 <input type="checkbox"/> mg/L  | 8 <input type="checkbox"/> |
| 43. Labeling index:                                  | <input type="text"/> %     |   | 8 <input type="checkbox"/> |
| 44. LDH:   | <input type="text"/>       | 1 <input type="checkbox"/> U/L 2 <input type="checkbox"/> μkat/L  | 8 <input type="checkbox"/> |

45. Upper limit of normal for LDH:

#### Quantitative Immunoglobulins:

#### Laboratory normal ranges:

- |          |                      |   |                            |
|----------|----------------------|---|----------------------------|
| 46. IgG: | <input type="text"/> | 1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L |                            |
|          |                      | 47. <input type="text"/> to <input type="text"/>  | 8 <input type="checkbox"/> |
| 48. IgA: | <input type="text"/> | 1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L |                            |
|          |                      | 49. <input type="text"/> to <input type="text"/>  | 8 <input type="checkbox"/> |
| 50. IgM: | <input type="text"/> | 1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L |                            |
|          |                      | 51. <input type="text"/> to <input type="text"/>  | 8 <input type="checkbox"/> |
| 52. IgD: | <input type="text"/> | 1 <input type="checkbox"/> mg/dL 3 <input type="checkbox"/> mg/L                                |                            |
|          |                      | 53. <input type="text"/> to <input type="text"/>  | 8 <input type="checkbox"/> |
| 54. IgE: | <input type="text"/> | 1 <input type="checkbox"/> IU/mL 2 <input type="checkbox"/> μg/L                                |                            |
|          |                      | 55. <input type="text"/> to <input type="text"/>  | 8 <input type="checkbox"/> |

For plasma cell leukemia:

- |  |                        |   |                            |
|--|------------------------|---|----------------------------|
| 31. Plasma cells in blood:                                 | <input type="text"/> % |   | 8 <input type="checkbox"/> |
| 31. <sup>2</sup> Absolute number of plasma cells in blood: | <input type="text"/>   | 1 <input type="checkbox"/> x 10 <sup>9</sup> /L (x 10 <sup>3</sup> /mm <sup>3</sup> ) 2 <input type="checkbox"/> x 10 <sup>6</sup> /L | 8 <input type="checkbox"/> |

TEAM:

IUBMID:

56. Was patient treated for multiple myeloma or plasma cell leukemia prior to high-dose therapy (conditioning)?

1  Yes 0  No Go to Q.189.<sup>2</sup>

Regimen	1st	2nd
<i>RADIATION THERAPY:</i> 57.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	90. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Specify sites: 58. <sup>2</sup>	_____	91. <sup>2</sup> _____
Date started: 62.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	95. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year
<i>CHEMOTHERAPY:</i> 64.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	97. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
# of cycles: 65.	<input type="text"/> <input type="text"/> <input type="checkbox"/> Unk or Not App	98. <input type="text"/> <input type="text"/> <input type="checkbox"/> Unk or Not App
Date started: 66.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	99. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year
<u>Treatment</u>		
Adriamycin: 68.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	101. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Cytosine arabinoside (Ara-C): 69.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	102. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Carmustine (BCNU): 70.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	103. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Chlorambucil: 70. <sup>2</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	103. <sup>2</sup> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Cyclophosphamide: 71.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	104. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Cisplatin: 72.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	105. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Dexamethasone: 73.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	106. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Etoposide (VP16): 74.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	107. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Idarubicin: 75.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	108. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Interferon: 75. <sup>2</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	108. <sup>2</sup> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Melphalan (LPAM): 76.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	109. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Mitoxantron: 77.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	110. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Prednisone: 78.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	111. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Vinblastine: 79.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	112. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Vincristine (VCR): 80.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	113. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Other: 81.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	114. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Specify: 82.	_____	115. _____
Other: 83.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	116. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Specify: 84.	_____	117. _____
Given for stem cell priming? 85. <sup>2</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	118. <sup>2</sup> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Best response: 86. <sup>2</sup> (check one only)	1 <input type="checkbox"/> Chemosensitive 2 <input type="checkbox"/> Chemoresistant 88 <input type="checkbox"/> Unknown	119. <sup>2</sup> 1 <input type="checkbox"/> Chemosensitive 2 <input type="checkbox"/> Chemoresistant 88 <input type="checkbox"/> Unknown
<span style="border: 1px solid black; border-radius: 10px; padding: 2px;">See Q.206 for definitions</span>		
Date response established: 87.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year 88 <input type="checkbox"/> Unknown	120. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year 88 <input type="checkbox"/> Unknown
Did patient relapse or progress? 88.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	121. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Date of relapse or progression: 89.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	122. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year

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Continued on next page

TEAM: [ ][ ][ ][ ]

IUBMID: [ ][ ][ ][ ][ ][ ][ ]

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Continued from previous page

Regimen	3rd	4th
<i>RADIATION THERAPY:</i> 123.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	156. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Specify sites: 124. <sup>2</sup>	_____	157. <sup>2</sup> _____
Date started: 128.	[ ][ ][ ][ ][ ][ ][ ] Month Day Year	161. [ ][ ][ ][ ][ ][ ][ ] Month Day Year
<i>CHEMOTHERAPY:</i> 130.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	163. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
# of cycles: 131.	[ ][ ] <input type="checkbox"/> Unk or Not App	164. [ ][ ] <input type="checkbox"/> Unk or Not App
Date started: 132.	[ ][ ][ ][ ][ ][ ][ ] Month Day Year	165. [ ][ ][ ][ ][ ][ ][ ] Month Day Year
<u>Treatment</u>		
Adriamycin: 134.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	167. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Cytosine arabinoside (Ara-C): 135.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	168. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Carmustine (BCNU): 136.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	169. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Chlorambucil: 136. <sup>2</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	169. <sup>2</sup> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Cyclophosphamide: 137.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	170. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Cisplatin: 138.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	171. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Dexamethasone: 139.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	172. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Etoposide (VP16): 140.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	173. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Idarubicin: 141.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	174. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Interferon: 141. <sup>2</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	174. <sup>2</sup> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Melphalan (LPAM): 142.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	175. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Mitoxantron: 143.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	176. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Prednisone: 144.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	177. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Vinblastine: 145.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	178. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Vincristine (VCR): 146.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	179. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Other: 147.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	180. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Specify: 148.	_____	181. _____
Other: 149.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	182. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Specify: 150.	_____	183. _____
Given for stem cell priming? 151. <sup>2</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	184. <sup>2</sup> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Best response: 152. <sup>2</sup> (check one only)	1 <input type="checkbox"/> Chemosensitive 2 <input type="checkbox"/> Chemoresistant 88 <input type="checkbox"/> Unknown	185. <sup>2</sup> 1 <input type="checkbox"/> Chemosensitive 2 <input type="checkbox"/> Chemoresistant 88 <input type="checkbox"/> Unknown
See Q.206 for definitions		
Date response established: 153.	[ ][ ][ ][ ][ ][ ][ ] Month Day Year 88 <input type="checkbox"/> Unknown	186. [ ][ ][ ][ ][ ][ ][ ] Month Day Year 88 <input type="checkbox"/> Unknown
Did patient relapse or progress? 154.	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	187. 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No
Date of relapse or progression: 155.	[ ][ ][ ][ ][ ][ ][ ] Month Day Year	188. [ ][ ][ ][ ][ ][ ][ ] Month Day Year

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TEAM:

IUBMID:

189.<sup>2</sup> Total number of chemotherapy regimens prior to conditioning of recipient for transplant:

190. At what point in the disease course was transplant performed?

- 1  As part of initial therapy in patients not progressing at any time prior to transplant
- 2  Later in the disease course in patients progressing at any time prior to transplant

**Status of myeloma or plasma cell leukemia just prior to start of high-dose therapy (conditioning):**

206. Indicate patient's sensitivity of myeloma to chemotherapy prior to conditioning (**Q.206 only: treatment must have been completed  $\leq$  6 months prior to transplant**):

- 1  Sensitive ( $\geq$ 50% reduction in Ig level, or  $\geq$ 90% reduction in urinary light chains in light chain only disease, or  $\geq$ 50% reduction of plasma cells in bone marrow for nonsecretory myeloma)
- 2  Resistant (<50% reduction of Ig level, or <90% reduction in urinary light chains in light chain only disease, or <50% reduction of plasma cells in bone marrow for nonsecretory myeloma)
- 3  Not applicable (no chemotherapy, or ended more than 6 months prior to conditioning)
- 88  Unknown

207. Indicate patient's disease status of multiple myeloma or plasma cell leukemia immediately prior to conditioning for transplant (refer to page 7 for definitions):

- 1  CR
- 2  CCR
- 3  PR
- 4  MR (multiple myeloma only)
- 5  NR
- 6  SD (multiple myeloma only)
- 7  REL from CR (untreated)
- 8  PROG
- 80  NE, specify reason: \_\_\_\_\_
- 88  Unknown
- 90  Other, specify: \_\_\_\_\_

208. Date patient achieved/began the disease status indicated in **Q.206**:

Month Day Year

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TEAM: IUBMID: **Response Codes****CR = Complete Response** requires *all* of the following:

- Absence of the original monoclonal paraprotein in serum and urine by routine electrophoresis and by immunofixation maintained for a minimum of 6 weeks. The presence of new monoclonal bands consistent with oligoclonal immune reconstitution does not exclude CR.
- <5% plasma cells in a bone marrow aspirate and also on trephine bone biopsy, if biopsy is performed. If absence of monoclonal protein is sustained for 6 weeks it is not necessary to repeat the bone marrow unless the patient had non-secretory myeloma.
- No increase in size or number of lytic bone lesions on radiological investigations, if performed (development of a compression fracture does not exclude response).
- Disappearance of soft tissue plasmacytomas.
- For plasma cell leukemia, absence of plasma cells in blood.

(Patients in whom some, but not all, the criteria for CR is fulfilled are classified as PR, providing the remaining criteria satisfy the requirements for PR. This includes patients in whom routine electrophoresis is negative but in whom immunofixation has not been performed.)

**CCR = Continuing Complete Response** requires *all* of the following:

- CR continuing from CR prior to conditioning.

**PR = Partial Response** requires the following:

- ≥50% reduction in the level of the serum monoclonal paraprotein, maintained for a minimum of 6 weeks.  
**OR**  
Reduction in 24 hour urinary light chain excretion either by ≥90% **or** to <200 mg/24 hours, maintained for a minimum of 6 weeks, in light chain disease.
- For patients with non-secretory myeloma or plasma cell leukemia only, ≥50% reduction in plasma cells in a bone marrow aspirate and on trephine biopsy, if biopsy is performed, maintained for a minimum of 6 weeks.
- ≥50% reduction in the size of soft tissue plasmacytomas (by radiography or clinical examination).
- No increase in size or number of lytic bone lesions on radiological investigations, if performed (development of a compression fracture does not exclude response).
- For plasma cell leukemia, absence of plasma cells in the blood.

(Patients in whom some, but not all, the criteria for PR are fulfilled are classified as MR, providing the remaining criteria satisfy the requirements for MR.)

**MR = Minimal Response** requires *all* of the following:

- 25-49% reduction in the level of the serum monoclonal paraprotein maintained for a minimum of 6 weeks.  
**OR**  
50-89% reduction in 24 hour urinary light chain excretion, which still exceeds 200 mg/24 hours, maintained for a minimum of 6 weeks.
- For patients with non-secretory myeloma only, 25-49% reduction in plasma cells in a bone marrow aspirate and on trephine biopsy, if biopsy is performed, maintained for a minimum of 6 weeks.
- 25-49% reduction in the size of soft tissue plasmacytomas (by radiography or clinical examination).

- No increase in the size or number of lytic bone lesions on radiological investigations, if performed (development of a compression fracture does not exclude response).

(MR also includes patients in whom some, but not all, the criteria for PR are fulfilled, provided the remaining criteria satisfy the requirements for MR.)

**NR = No Response**

- Not meeting the criteria of either minimal response or progressive disease.
- For plasma cell leukemia only, not meeting criteria for CR or PR.

**SD = Stable Disease**

- Stable values (within 25% above or below value at time response is assessed) maintained for at least 3 months.

**REL from CR = Relapse from CR** requires one or more of the following:

- Reappearance of serum or urine paraprotein on immunofixation or routine electrophoresis, confirmed by at least one further investigation and excluding oligoclonal immune reconstitution.

- ≥5% plasma cells in a bone marrow aspirate or on trephine bone biopsy.

- Development of new lytic bone lesions or soft tissue plasmacytomas or definite increase in the size of residual bone lesions. Development of a compression fracture does not exclude continued response and may not indicate progression.

- Development of hypercalcaemia (corrected serum Ca >11.5 mg/dl or >2.8 mmol/L) not attributable to any other cause.

- For plasma cell leukemia, reappearance of plasma cells in blood.

**PROG = Progressive Disease** (for patients not in CR) requires one or more of the following:

- >25% increase in the level of the serum monoclonal paraprotein, which must also be an absolute increase of at least 5 g/L and confirmed by at least one repeated investigation.

- >25% increase in 24 hour urinary light chain excretion, which must also be an absolute increase of at least 200 mg/24 hours and confirmed by at least one repeated investigation.

- >25% increase in plasma cells in a bone marrow aspirate or on trephine biopsy, which must also be an absolute increase of at least 10%.

- Definite increase in the size of existing bone lesions or soft tissue plasmacytomas.

- Development of new bone lesions or soft tissue plasmacytomas (development of a compression fracture does not exclude continued response and may not indicate progression).

- Development of hypercalcaemia (corrected serum Ca >11.5 mg/dl or >2.8 mmol/L) not attributable to any other cause.

- For plasma cell leukemia, reappearance of plasma cells in blood.

TEAM:

IUBMID:

### Hematologic and Clinical Parameters Just Prior to Start of High-dose Therapy (Conditioning)

		<u>Specify Units</u>	<u>Unknown</u>
213.	Plasma cells in bone marrow (Aspirate): <input type="text"/> <input type="text"/> <input type="text"/> %	214. 1 <input type="checkbox"/> Source (aspirate vs biopsy) unknown	8 <input type="checkbox"/>
215.	Plasma cells in bone marrow (Biopsy): <input type="text"/> <input type="text"/> <input type="text"/> %		8 <input type="checkbox"/>
216.	Serum calcium: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> mmol/L 3 <input type="checkbox"/> mEq/L	8 <input type="checkbox"/>
217.	Serum albumin: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> g/dl 2 <input type="checkbox"/> g/L	8 <input type="checkbox"/>
219.	Serum creatinine: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> mmol/L 3 <input type="checkbox"/> $\mu$ mol/L	8 <input type="checkbox"/>
220.	Serum monoclonal Ig (only from electrophoresis): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	8 <input type="checkbox"/>
221.	Urinary monoclonal light chains: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> g/24h		8 <input type="checkbox"/>
222.	Serum $\beta_2$ -microglobulin: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> $\mu$ g/dL 2 <input type="checkbox"/> mg/L 3 <input type="checkbox"/> nmol/L	8 <input type="checkbox"/>
223.	C-reactive protein: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> mg/L	8 <input type="checkbox"/>
224.	Labeling index: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> %		8 <input type="checkbox"/>
225.	LDH: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> U/L 2 <input type="checkbox"/> $\mu$ kat/L	8 <input type="checkbox"/>
226. Upper limit of normal for LDH: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>			

<u>Quantitative Immunoglobulins:</u>		<u>Laboratory normal ranges:</u>	
227.	IgG: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	
228.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	to	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> 8 <input type="checkbox"/>
229.	IgA: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	
230.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	to	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> 8 <input type="checkbox"/>
231.	IgM: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	
232.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	to	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> 8 <input type="checkbox"/>
233.	IgD: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> mg/dL 3 <input type="checkbox"/> mg/L	
234.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	to	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> 8 <input type="checkbox"/>
235.	IgE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> IU/mL 2 <input type="checkbox"/> $\mu$ g/L	
236.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	to	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> 8 <input type="checkbox"/>

For plasma cell leukemia:			
211.	Plasma cells in blood: <input type="text"/> <input type="text"/> %		8 <input type="checkbox"/>
212. <sup>2</sup>	Absolute number of plasma cells in blood: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	1 <input type="checkbox"/> $\times 10^9/L$ ( $\times 10^3/mm^3$ ) 2 <input type="checkbox"/> $\times 10^6/L$	8 <input type="checkbox"/>

Retired - Not for Data Submission



TEAM:

IUBMID:

237.<sup>2</sup> Were cytogenetics done on bone marrow anytime prior to high-dose therapy (conditioning)?

- 1  Yes, normal (46,XX or 46,XY)
- 2  Yes, but no evaluable metaphases
- 3  Yes, abnormal
- 0  No
- 8  Unknown

Specify abnormalities:

Yes No Unknown

- 237.<sup>3</sup> 1  0  8  Trisomy 3(+3)
- 237.<sup>4</sup> 1  0  8  Trisomy 5(+5)
- 237.<sup>5</sup> 1  0  8  Trisomy 7(+7)
- 237.<sup>6</sup> 1  0  8  Trisomy 9(+9)
- 237.<sup>7</sup> 1  0  8  Trisomy 11(+11)
- 237.<sup>8</sup> 1  0  8  Trisomy 15(+15)
- 237.<sup>9</sup> 1  0  8  Trisomy 19(+19)
- 237.<sup>10</sup> 1  0  8  Monosomy 13(-13)
- 237.<sup>11</sup> 1  0  8  Abnormal 8q24
- 237.<sup>12</sup> 1  0  8  Abnormal 11q13
- 237.<sup>13</sup> 1  0  8  Abnormal 13q14
- 237.<sup>14</sup> 1  0  8  Abnormal 14q32

*If Cytogenetics Report is available,  
check here , attach copy and reference Q.237.<sup>2</sup>*

250.<sup>2</sup> Was amyloidosis present at any time?

- 1  Yes
- 0  No
- 8  Unknown

Specify:

	Site of Involvement			Documented by Biopsy?		
	Yes	No	Unknown	Yes	No	Unknown
252. Skin	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	265. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
253. Subcutaneous tissue	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	266. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
254. Carpal ligament	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	267. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
255. Peripheral nerve	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	268. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
256. Heart	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	269. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
257. Liver	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	270. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
258. Rectum	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	271. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
259. Other Organ	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	272. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
260. Kidney	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	273. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
261. Bone marrow	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	274. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
262. Tongue	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	275. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
263. Other,	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>			

Specify: \_\_\_\_\_

Retired - Not for Data Submission

TEAM: [ ][ ][ ][ ]

IUBMID: [ ][ ][ ][ ][ ][ ]

### Posttransplant Information\*

*\*To be completed 100 days posttransplant, or at time of death if death occurred <100 days posttransplant, or immediately prior to start of high-dose therapy (conditioning) for second transplant if second transplant done <100 days after first transplant.*

#### Hematologic and Clinical Parameters at the Time of Best Response, ≤Day 100 Posttransplant

289.<sup>2</sup> Best response posttransplant (see Response Codes on page 7):

- 1  CR
- 2  CCR
- 3  PR
- 4  MR (multiple myeloma only)
- 5  NR
- 6  SD (multiple myeloma only)
- 7  REL from CR (untreated)
- 8  PROG
- 19  NE

- 289.<sup>3</sup> Date CR first documented:
- 289.<sup>4</sup> Date of best response determination:
- 289.<sup>5</sup> Date of best response determination:
- 289.<sup>6</sup> Date of best response determination:
- 289.<sup>7</sup> Date of best response determination:
- 289.<sup>8</sup> Date of best response determination:
- 291. Date of relapse:
- 290. Date of progression:
- 292. Specify reason: \_\_\_\_\_

Month	Day	Year
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
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[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]

- 294. Plasma cells in bone marrow (Aspirate): [ ][ ][ ] % Specify Units Unknown
- 295.  Source (aspirate vs biopsy) unknown 8
- 296. Plasma cells in bone marrow (Biopsy): [ ][ ][ ] % 8
- 297. Serum monoclonal Ig (only from electrophoresis): [ ][ ][ ][ ] 1  mg/dL 2  g/dL 3  g/L 8
- 297.<sup>2</sup> Serum immunofixation: 0  Negative 1  Positive Specify (check all that apply): 8 

**Yes No**

297.<sup>3</sup> 1  0  Original monoclonal band

297.<sup>4</sup> 1  0  New monoclonal band(s)
- 298. Urinary monoclonal light chains: [ ][ ][ ] . [ ][ ] g/24h 8
- 298.<sup>2</sup> Urinary immunofixation: 0  Negative 1  Positive Specify (check all that apply): 8 

**Yes No**

298.<sup>3</sup> 1  0  Original monoclonal band

298.<sup>4</sup> 1  0  New monoclonal band(s)
- 299. Serum β<sub>2</sub>-microglobulin: [ ][ ][ ] . [ ][ ][ ] 1  μg/dL 2  mg/L 3  nmol/L 8

- Quantitative Immunoglobulins:
- 303. IgG: [ ][ ][ ][ ] . [ ][ ][ ] 1  mg/dL 2  g/dL 3  g/L 8
  - 305. IgA: [ ][ ][ ][ ] . [ ][ ][ ] 1  mg/dL 2  g/dL 3  g/L 8
  - 306. IgM: [ ][ ][ ][ ] . [ ][ ][ ] 1  mg/dL 2  g/dL 3  g/L 8
  - 309. IgD: [ ][ ][ ][ ] . [ ][ ][ ] 1  mg/dL 3  mg/L 8
  - 311. IgE: [ ][ ][ ][ ] . [ ][ ][ ] 1  IU/mL 2  μg/L 8



TEAM: [ ][ ][ ][ ]

IUBMID: [ ][ ][ ][ ][ ][ ][ ]

**Current Disease Status**

329. Date of current disease status determination: [ ][ ] [ ][ ] [ ][ ][ ][ ]  
Month Day Year

330. Is current disease status the same as best response, as indicated in Q.289.2? 1  Yes 0  No

331. **Current response** status of myeloma or plasma cell leukemia (see Response Codes on page 7):

- 1  CR
- 3  PR
- 4  MR (multiple myeloma only)
- 7  REL from CR (untreated)
- 8  PROG
- 80  NE

- 331.2 Date CR established:
- 331.3 Date PR established:
- 331.4 Date MR established:
- 332.2 Date of relapse:
- 332.3 Reappearance of original monoclonal band in serum and/or urine immunofixation only? 1  Yes 0  No 3  Unknown
- 332.4 Date of progression:
- 333. Specify reason: \_\_\_\_\_

Month	Day	Year
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]
[ ][ ]	[ ][ ]	[ ][ ][ ]

**Current Laboratory Values if Further Myeloma/Plasma Cell Leukemia Therapy has not been Given**

	Specify Units	Unknown
333.2 Plasma cells in bone marrow (Aspirate): [ ][ ][ ] %		
333.4 Plasma cells in bone marrow (Biopsy): [ ][ ][ ] %		8 <input type="checkbox"/>
340. Serum monoclonal Ig (only from electrophoresis): [ ][ ][ ]	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	8 <input type="checkbox"/>
340.2 Serum immunofixation: 0 <input type="checkbox"/> Negative 1 <input type="checkbox"/> Positive	Specify (check all that apply): Yes No 340.3 1 <input type="checkbox"/> 0 <input type="checkbox"/> Original monoclonal band 340.4 1 <input type="checkbox"/> 0 <input type="checkbox"/> New monoclonal band(s)	8 <input type="checkbox"/>
341. Urinary monoclonal light chains: [ ][ ][ ] . [ ] g/24h		8 <input type="checkbox"/>
341.2 Urinary immunofixation: 0 <input type="checkbox"/> Negative 1 <input type="checkbox"/> Positive	Specify (check all that apply): Yes No 341.3 1 <input type="checkbox"/> 0 <input type="checkbox"/> Original monoclonal band 341.4 1 <input type="checkbox"/> 0 <input type="checkbox"/> New monoclonal band(s)	8 <input type="checkbox"/>
Quantitative immunoglobulins:		
346. IgG: [ ][ ][ ][ ] . [ ][ ]	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	8 <input type="checkbox"/>
348. IgA: [ ][ ][ ][ ] . [ ][ ]	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	8 <input type="checkbox"/>
350. IgM: [ ][ ][ ][ ] . [ ][ ]	1 <input type="checkbox"/> mg/dL 2 <input type="checkbox"/> g/dL 3 <input type="checkbox"/> g/L	8 <input type="checkbox"/>
352. IgD: [ ][ ][ ][ ] . [ ][ ]	1 <input type="checkbox"/> mg/dL 3 <input type="checkbox"/> mg/L	8 <input type="checkbox"/>
354. IgE: [ ][ ][ ][ ] . [ ][ ]	1 <input type="checkbox"/> IU/mL 2 <input type="checkbox"/> µg/L	8 <input type="checkbox"/>
For plasma cell leukemia:		
354.2 Plasma cells in blood: [ ][ ] %		8 <input type="checkbox"/>
354.3 Absolute number of plasma cells in blood: [ ][ ][ ][ ][ ] . [ ][ ]	1 <input type="checkbox"/> x 10 <sup>9</sup> /L (x 10 <sup>3</sup> /mm <sup>3</sup> ) 2 <input type="checkbox"/> x 10 <sup>6</sup> /L	8 <input type="checkbox"/>
354.4 Was a molecular marker (i.e., CDRIII) tested?	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	8 <input type="checkbox"/>
354.5 Specify type and result: _____		

