Form 2556 R1.0: Myelofibrosis CMS Study Supplemental Pre-HCT Data

Key Fields

Sequence Number:  __ __ __ __
Date Received:  __ __ __ __ - __ __- __ __
CIBMTR Center Number:  __ __ __ __
CIBMTR Research ID:  __ __ __ __ __
Event date:  __ __ __ __ - __ __- __ __

HCT type: (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product type: (check all that apply)
- Bone marrow
- PBSC
- Single cord blood unit
- Multiple cord blood units
- Other product

Specify other method:

DIPSS Prognosis Score

Questions: 1 - 17

1 Specify the maximum DIPSS score the patient ever achieved:

2 Specify when maximum DIPSS score was documented
   - At diagnosis
   - Between diagnosis and the preparative regimen
   - At last evaluation prior to the start of the preparative regimen

Report the clinical and laboratory assessments used to determine the maximum DIPSS score:

3 WBC

   - Known
   - Unknown

4 _____ x 10^9/L (x 10^3/mm^3)
   - Known
   - Unknown

5 Date sample collected:  __ __ __ __

6 Hemoglobin

   - Known
   - Unknown

7 _____ g/dL  g/L  mmol/L

8 Date sample collected:  __ __ __ __

9 Was RBC transfused ≤ 30 days before date of test?
   - Yes
   - No

10 Platelets

   - Known
   - Unknown

11 _____ x 10^9/L (x 10^3/mm^3)

12 Date sample collected:  __ __ __ __

13 Were platelets transfused ≤ 7 days before date of test?
   - Yes
   - No

14 Blasts in blood

   - Known
   - Unknown

15 _____ %

16 Date sample collected:  __ __ __ __

17 Did the recipient have constitutional symptoms? (> 10% weight loss in 6 months, night sweats, unexplained fever higher than 37.5°C)
   - Yes
   - No

Mail, fax or email this form to Minneapolis. Fax: 612-527-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.
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Pre-HCT JAK1 and JAK2 Inhibitor Therapy

Questions: 18 - 33

18 Did the recipient receive JAK1 or JAK2 inhibitor therapy? (pre-HCT)
   • Yes
   • No

Specify therapy given:

19 Ruxolitinib (Jakafi)
   • Yes
   • No

20 Date therapy started
   • Known
   • Unknown

21 Date started: __ __ __ __ __ __ __ __ __

22 Date therapy stopped
   • Known
   • Unknown

23 Date stopped: __ __ __ __ __ __ __ __ __

24 Specify the reason therapy stopped
   • Toxicity (e.g. cytopenias)
   • Not tolerable
   • Lack of response
   • Disease progression
   • Other
   • Unknown

25 Specify other reason:

26 Other JAK1 or JAK2 inhibitor
   • Yes
   • No

27 Specify other JAK1 or JAK2 inhibitor:

28 Date therapy started
   • Known
   • Unknown

29 Date started: __ __ __ __ __ __ __ __ __

30 Date therapy stopped
   • Known
   • Unknown

31 Date stopped: __ __ __ __ __ __ __ __ __

Pre-HCT JAK1 and JAK2 Inhibitor Therapy (1)

Questions: 19 - 31

32 Response to therapy
   • Clinical improvement: defined as 50% improvement in palpable spleen length for spleen palpable by 10 cm, or complete resolution of splenomegaly for palpable spleen size <10 cm
   • Stable disease
   • Non-splenectomy disease progression: increase in blasts to 10% to 19%, intolerance to treatment due to hematologic/non-hematologic side effects, or new onset transfusion-requiring anemia
   • Splenic disease: appearance of new splenomegaly palpable 5 cm below costal margin (BCM) or 100% increase in palpable disease BCM for baseline splenomegaly of 5 cm or progression requiring splenectomy to 10 cm BCM, 50% increase in palpable disease BCM for baseline splenomegaly of 10 cm BCM, loss of spleen response, or symptomatic splenomegaly progression requiring splenectomy
   • Transformation to leukemia: peripheral blood or bone marrow blast count of 20%

33 Date assessed: __ __ __ __ __ __ __ __ __

Laboratory Studies Prior to Therapy

Questions: 34 - 71

Specify the laboratory values immediately prior to JAK1 / JAK2 inhibitor therapy. If no JAK1 / JAK2 inhibitor therapy was given, report results at last evaluation prior to the start of the preparative regimen:

34 Was presence of somatic mutations tested? (immediately prior to JAK2 inhibitor therapy initiation)
   • Yes
   • No
   • Unknown

35 Date sample collected: __ __ __ __ __ __ __ __ __

36 Specify the cell source
   • Bone marrow
   • Peripheral blood
### Laboratory Studies Prior to Therapy (1)

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>37 JAK 2</td>
<td>Positive</td>
</tr>
<tr>
<td>38 CALR1</td>
<td>Positive</td>
</tr>
<tr>
<td>39 CALR2</td>
<td>Positive</td>
</tr>
<tr>
<td>40 MPL</td>
<td>Positive</td>
</tr>
<tr>
<td>41 ASXL1</td>
<td>Positive</td>
</tr>
<tr>
<td>42 SRSF2</td>
<td>Positive</td>
</tr>
<tr>
<td>43 EZH2</td>
<td>Positive</td>
</tr>
<tr>
<td>44 IDH1</td>
<td>Positive</td>
</tr>
<tr>
<td>45 IDH2</td>
<td>Positive</td>
</tr>
<tr>
<td>46 LNK</td>
<td>Positive</td>
</tr>
<tr>
<td>47 CBL</td>
<td>Positive</td>
</tr>
<tr>
<td>48 TET2</td>
<td>Positive</td>
</tr>
<tr>
<td>49 IKZF1</td>
<td>Positive</td>
</tr>
<tr>
<td>50 DNMT3A</td>
<td>Positive</td>
</tr>
<tr>
<td>51 TP53</td>
<td>Positive</td>
</tr>
<tr>
<td>52 SF3B1</td>
<td>Positive</td>
</tr>
<tr>
<td>53 U2AF1</td>
<td>Positive</td>
</tr>
<tr>
<td>54 FLT3</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**Laboratory Studies Prior to Therapy (1)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 Other gene mutation</td>
<td>Positive</td>
</tr>
<tr>
<td>56 Specify other gene mutation:</td>
<td></td>
</tr>
</tbody>
</table>

**Questions: 55 - 56**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>57 WBC</td>
<td>Known</td>
</tr>
<tr>
<td>58 [ ] 10^9/L (x 10^3/mm3)</td>
<td>x 10^6/L</td>
</tr>
<tr>
<td>59 Date sample collected:</td>
<td></td>
</tr>
<tr>
<td>60 Hemoglobin</td>
<td>Known</td>
</tr>
</tbody>
</table>
61. Date sample collected: __ __ __ __ - __ __- __ __

62. Was RBC transfused ≤ 30 days before date of test?
   - Yes
   - No

63. Specify the reason therapy stopped
   - Toxicity
   - Positive
   - Stable disease
   - Disease progression
   - Not tolerable
   - Other JAK1 or JAK2 inhibitor
   - Ruxolitinib (Jakafi)
   - JAK 2
   - ASXL1
   - CALR1
   - Other gene mutation
   - Unknown

64. Platelets
   - Known
   - Unknown

65. Date sample collected: __ __ __ __ - __ __- __ __

66. Were platelets transfused ≤ 7 days before date of test?
   - Yes
   - No

67. CD34+ cells (peripheral blood)
   - Known
   - Unknown

68. Blasts in blood
   - Known
   - Unknown

69. Date sample collected: __ __ __ __ - __ __- __ __

70. Did the recipient have constitutional symptoms? (> 10% weight loss in 6 months, night sweats, unexplained fever higher than 37.5°C)
   - Yes
   - No

71. Laboratory Studies at Last Evaluation Prior to HCT
   Questions: 72 - 76

72. Total serum ferritin
   - Known
   - Unknown

73. Date sample collected: __ __ __ __ - __ __- __ __

74. CD34+ cells (peripheral blood)
   - Known
   - Unknown

75. Disease Assessment at the Time of HCT
   Questions: 77 - 90

76. Date therapy stopped: __ __ __ __ - __ __- __ __

77. Did the recipient have evidence of pulmonary hypertension at HCT?
   - Yes
   - No
   - Unknown

78. Did the recipient have evidence of portal hypertension at HCT?
   - Yes
   - No
   - Unknown

79. Hepatomegaly
   - yes
   - no

80. Specifying the liver size: __ __ __ __ centimeters below right costal margin

81. Specifying the spleen size: __ __ __ __ centimeters below right costal margin

82. Spleen size
   - Known
   - Unknown
   - Not applicable (splenectomy)

83. Serum ferritin
   - Known
   - Unknown
   - Not done
   - Negative
   - No

84. Liver MRI
   - Known
   - Unknown
   - Not done
   - Negative
   - No

85. Other method
   - Known
   - Unknown
   - Not done
   - Negative
   - No
Questions: 72 - 76
No
3
Questions: 77 - 90
Unknown
Negative
Negative
Not done
e.g., cytopenia
x 10
No
mmol/L
Negative
g/dL
Negative
No
Not done
Questions: 18 - 33
Unknown
Negative
Negative
Negative
No
Unknown
Unknown
% Negative
Not done
No
Unknown
Questions: 19 - 31
Negative

Specify when maximum DIPSS score was documented