All these CDEs are Supplemental. Reference: CIBMTR

**POST THERAPY DATA FORM**

**Visit:**

[ ]  3 month

[ ]  6 month

[ ]  9 month

[ ]  12 month

[ ]  15 month

[ ]  18 month

[ ]  21 month

[ ]  24 month

[ ]  30 month

[ ]  36 month

[ ]  42 month

[ ]  48 month

[ ]  5 years or greater. Number of Years: \_\_\_\_\_\_\_\_\_\_\_\_

Report all findings SINCE DATE OF LAST REPORT:

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Date of examination: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Physical assessments:

(to be decided)

Date of initial gene therapy: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Has the patient received additional gene therapy since the last report?

[ ]  Yes

[ ]  No

If yes, date: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

**NEUTROPHIL RECOVERY**

*To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.*

Was there evidence of initial granulopoietic recovery?

[ ]  Yes (ANC ≥ 500/mm3 achieved and sustained for 3 lab values)

[ ]  No (ANC ≥ 500/mm3 was not achieved)

Not applicable (ANC never dropped below 500/mm3 at any time after the start of the preparative regimen)

Date ANC ≥ 500/mm³ (first of 3 lab values):
 \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Following the initial granulopoietic recovery, was there subsequent decline in ANC to < 500/mm3 for ≥ 3 days since the date of last report?

[ ]  Yes

[ ]  No

Date of decline in ANC to < 500/mm3 for ≥ 3 days (first of 3 days that the ANC declined):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Did recipient recover and maintain ANC ≥ 500/mm3 following the decline?

[ ]  Yes

[ ]  No

Date of ANC recovery (first of 3 lab values):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

**PLATELET RECOVERY**

*This section relates to initial platelet recovery. All dates should reflect no transfusions in the previous 7 days. To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.*

Was there evidence of initial thrombopoietic recovery?

[ ]  Yes (PLT ≥ 50 x 109/L achieved untransfused for 7 days and sustained for 3 lab values)

[ ]  No (PLT ≥ 50 x 109/L was not achieved)

[ ]  Not applicable (PLT never dropped below 50 x 109/L at any time after the start of the preparative regimen)

Date PLT ≥ 50 x 109/L (first of 3 lab values): \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Following the initial thrombopoietic recovery, was there subsequent decline in PLT < 50 x 109/L for ≥ 3 days since the date of last report?

[ ]  Yes

[ ]  No

Date of decline in PLT < 20 x 109/L for ≥ 3 days (first of 3 days that the PLT declined):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Did recipient recover and maintain PLT ≥ 20 x 109/L following the decline?

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Date of PLT recovery (first of 3 lab values):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Date PLT ≥ 50 x 109/L (first of 3 lab values):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Following thrombopoietic recovery PLT ≥ 50 x 109/L, was there subsequent decline in PLT to < 50 x 109/L for ≥ 3 days since the date of last report?

 [ ]  Yes (PLT ≥ 50 x 109/L achieved and sustained for 3 lab values)

[ ]  No (PLT ≥ 50 x 109/L was not achieved)

[ ]  Not applicable (PLT never dropped below 50 x 109/L at any time after the start of the preparative regimen)

Date of decline in PLT < 50 x 109/L for ≥ 3 days (first of 3 days that the PLT declined):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Did recipient recover and maintain PLT ≥ 50 x 109/L following the decline?

[ ]  Yes (PLT ≥ 50 x 109/L achieved and sustained for 3 lab values)

[ ]  No (PLT ≥ 50 x 109/L was not achieved)

Date of PLT recovery (first of 3 lab values):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

 Date PLT ≥ 100 x 109/L (first of 3 lab values):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Following thrombopoietic recovery PLT ≥ 100 x 109/L, was there subsequent decline in PLT to
< 100 x 109/L for ≥ 3 days since the date of last report?

 [ ]  Yes (PLT ≥ 100 x 109/L achieved and sustained for 3 lab values)

[ ]  No (PLT ≥ 100 x 109/L was not achieved)

[ ]  Not applicable (PLT never dropped below 100 x 109/L at any time after the start of the preparative regimen)

Date of decline in PLT < 100 x 109/L for ≥ 3 days (first of 3 days that the PLT declined):

 \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Did recipient recover and maintain PLT ≥ 100 x 109/L following the decline?

Date of PLT recovery (first of 3 lab values):

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

**ERYTHROCYTE RECOVERY**

*This section relates to initial hemoglobin recovery. All dates should reflect no transfusions in the previous 90 days. To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.*

Was there evidence of initial erythropoietic recovery?

[ ]  Yes (Hb ≥ 10 g/dL achieved and sustained for 3 lab values without transfusion)

[ ]  No (Hb ≥ 10 g/dL was not achieved)

[ ]  No Patient continues to receive RBC transfusions

[ ]  Not applicable (Hb never dropped below 10 g/dL at any time after the start of the preparative

regimen)

Date Hb ≥ 10 g/dL (first of 3 lab values) without transfusion:

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Hemoglobin \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Erythrocyte count: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Absolute reticulocyte count: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lactate dehydrogenase: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bilirubin (indirect) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Following the initial erythropoietic recovery, was there subsequent decline in Hb < 10 g/dL for ≥ 3 days since the date of last report?

[ ]  Yes

[ ]  No

Date of decline in Hb < 10 g/dL for ≥ 3 days (first of 3 days that the Hgb declined):

MCV: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Erythrocyte count: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Absolute reticulocyte count: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Lactate dehydrogenase: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Bilirubin (indirect) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did recipient recover and maintain Hb ≥ 10 g/dL following the decline?

[ ]  Yes

[ ]  No

Date of Hb recovery (first of 3 lab values):

MCV: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Erythrocyte count: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Absolute reticulocyte count: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Lactate dehydrogenase: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Bilirubin (indirect) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**GROWTH FACTOR AND CYTOKINE SUPPORT**

Did the recipient receive hematopoietic growth factors or cytokines after the start of the preparatory regimen?

Specify granulopoietic agent:

[ ]  G-CSF

[ ]  Peg G-CSF

[ ]  GM-CSF

[ ]  Other

Date started: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Indication: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Planned therapy per protocol

[ ]  Intervention for delay in cell count recovery

[ ]  Intervention for decline in cell count

[ ]  Other

Date ended \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_:

Specify thrombopoietic agent:

[ ]  Romiplostim

[ ]  Eltrombopag

[ ]  Avatrombopag

[ ]  Lusutrombopag

[ ]  Oprelvekin

[ ]  Other

Date started: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Indication: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

[ ]  Planned therapy per protocol

[ ]  Intervention for delay in cell count recovery

[ ]  Intervention for decline in cell count

[ ]  Other

 Date ended: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Specify erythropoietic agent:

[ ]  Epoetin alfa

[ ]  Darbepoetin

[ ]  Other

Date started: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Indication: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

[ ]  Planned therapy per protocol

[ ]  Intervention for delay in Hb recovery

[ ]  Intervention for decline in Hb count

[ ]  Other

 Date ended: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

**CURRENT HEMATOLOGICAL INDICES**

Date drawn: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

[ ]  White Blood Cell (WBC)

[ ]  Red Blood Cell (RBC)

[ ]  Hemoglobin (Hb)

[ ]  Hematocrit (HCT)

[ ]  Mean Cell Volume (MCV)

[ ]  Mean Cell Hemoglobin (MCH)

[ ]  Mean Cell Hb Conc (MCHC)

[ ]  Red Cell Dist Width (RDW)

[ ]  Reticulocyte %

[ ]  Absolute reticulocyte count

[ ]  Platelet count

[ ]  Mean Platelet Volume

[ ]  WBC Differential

[ ]  Neutrophil %

[ ]  Lymphocyte %

[ ]  Monocyte %

[ ]  Eosinophil %

[ ]  Basophil %

[ ]  Neutrophil, Absolute

[ ]  Lymphocyte, Absolute

[ ]  Monocyte, Absolute

[ ]  Eosinophil, Absolute

[ ]  Basophil, Absolute

**HEMOGLOBIN ELECTROPHORESIS**

Was hemoglobin electrophoresis performed? *(do not include results if an RBC transfusion occurred within 4 weeks of the electrophoresis study)*

[ ]  Yes

Date: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

[ ]  No

[ ]  Not Applicable (transfused within the last month)

Method:

[ ]  Gel based electrophoresis

[ ]  High-pressure liquid chromatography

[ ]  Capillary zone electrophoresis

[ ]  Isoelectric focusing

[ ]  Other

Specify the allele types:

HbA1

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

HbA2

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

HbC

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

HbS

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

HbF

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

Other (specify)

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

Other (specify)

[ ]  Yes \_\_\_\_\_\_\_%

[ ]  No

**General Instructions**

All these CDEs are Supplemental. Reference: CIBMTR