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