**MDS/MPN Response Criteria**

**MDS Response Criteria**

**Complete Remission (CR)**

*Requires all of the following maintained for a minimum of four weeks:*

**Bone marrow evaluation:**

- < 5% myeloblasts with normal maturation of all cell lines

**Peripheral blood evaluation:**

- Hemoglobin ≥ 11 g/dL untransfused without erythropoietic support
- ANC ≥ 1000/mm³ without myeloid growth factor support
- Platelets ≥ 100,000/mm³ without thrombopoietic support
- 0% blasts in blood

Alternative CR criteria are accepted in the setting of pediatric MDS and are as follows:

- Complete donor chimerism (≥ 95% donor chimerism without recipient cells detected)
- Hemoglobin ≥ 11 g/dL untransfused without erythropoietic support
- ANC ≥ 1000/mm³ without myeloid growth factor support
- Platelets ≥ 100,000/mm³ without thrombopoietic support

In some cases, there may not be a four-week interval between completion of therapy and the pre-transplant disease assessment. In this case, CR should still be reported as the status at transplant since it represents the “best assessment” prior to HCT. This is an exception to the criteria that CR be durable beyond four weeks; the pre-transplant disease status should not be changed based on early relapse or disease assessment post-transplant.
Hematologic Improvement (HI)

Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:

Hematologic improvement – erythropoietic (HI-E):

- Hemoglobin increase of \(\geq 1.5 \text{ g/dL} \) untransfused
  - or
- For RBC transfusions performed for hemoglobin \(\leq 9.0\): reduction in RBC units transfused in 8 weeks by \(\geq 4\) units compared to the number of units transfused in the 8 weeks prior to treatment

Hematologic improvement – platelets (HI-P):

- For pre-treatment platelet count of \(\geq 20 \times 10^9\), platelet absolute increase of \(\geq 30 \times 10^9\)
- For pre-treatment platelet count of \(< 20 \times 10^9\), platelet absolute increase of \(\geq 20 \times 10^9\) and \(\geq 100\%\) increase from pre-treatment level

Hematologic improvement – neutrophils (HI-N):

- Neutrophil count increase of \(\geq 100\%\) from pre-treatment level and an absolute increase of \(\geq 500/\text{mm}^3\)

No Response (NR)/Stable Disease (SD)

Does not meet the criteria for at least HI, but no evidence of disease progression to AML

Progression from Hematologic Improvement (Prog from HI)

Requires at least one of the following in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.):

- \(\geq 50\%\) reduction from maximum response levels in granulocytes or platelets
- Reduction in hemoglobin by \(\geq 1.5\ \text{ g/dL} \)

* Hypomethylating agents (e.g. Vidaza) should not be considered cytotoxic therapy; therefore, Hematologic Improvement may still be reported if the recipient meets the criteria below while continuing to receive hypomethylating agents.
Transfusion dependence

Note: declining donor chimerism does not meet the criteria for progression. If the above criteria for progression have been met, but a hematologic improvement was not previously achieved, report “No Response (NR) / Stable Disease (SD)”.

Relapse from Complete Remission (Rel from CR)

Requires at least one of the following:

- Return to pre-treatment bone marrow blast percentage
- Decrease of ≥ 50% from maximum response levels in granulocytes or platelets
- Transfusion dependence or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy

Note: declining donor chimerism does not meet the criteria for relapse.

Progression to AML

≥ 20% blasts in the blood or bone marrow

MPN Response Criteria

CR (requires each of the following)

- Bone marrow with ≤ 5% myeloblasts (including monocytic blast equivalents in CMML) with normal maturation of all cell lines and return to normal cellularity
- Myelofibrosis absent or ≤ grade 1 fibrosis (mild reticulin fibrosis)
- Peripheral blood counts showing:
  - WBC ≤ 10 × 10^9/L
  - Hgb ≥ 11 g/dL
  - PLT ≥ 100 × 10^9/L; ≤ 450 × 10^9/L
  - Blasts 0%
  - Neutrophilic precursors reduced to ≤ 2%
  - Monocytes ≤ 1 × 10^9/L
- Resolution of any extramedullary disease present prior to therapy; this includes cutaneous disease, disease-related serous effusions, and palpable hepatosplenomegaly

Myelofibrosis CR
• Bone marrow with ≤ 5% myeloblasts with normal maturation of all cell lines
• Myelofibrosis absent or ≤ grade 1 fibrosis (mild reticulin fibrosis)
• Peripheral blood counts showing:
  ◦ ANC ≥ 1.0 × 10^9/L and < upper limit of normal
  ◦ Hgb ≥ 11 g/dL and < upper limit of normal
  ◦ PLT ≥ 100 × 10^9/L and < upper limit of normal
  ◦ Neutrophilic precursors reduced to ≤ 2%
• Resolution of disease symptoms and no palpable hepatosplenomegaly; no evidence of extramedullary hematopoiesis

Hematologic Improvement

Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:

• Response of erythroid line requires:
  ◦ Hgb increase ≥ 2.0 g/dL from baseline
  ◦ Transfusion independence for patients requiring at least 4 packed RBC transfusions in the previous 8 weeks
• Response of platelets requires:
  ◦ For pre-treatment platelet count of > 20 × 10^9/L, platelet absolute increase of ≥ 30 × 10^9/L
  ◦ For pre-treatment platelet count of ≤ 20 × 10^9/L, platelet absolute increase of ≥ 20 × 10^9/L and ≥ 100% increase from pre-treatment level
• Response of neutrophils requires:
  ◦ For pre-treatment ANC > 0.5 × 10^9/L and ≤ 1.0 × 10^9/L, neutrophils with ≥ 50% increase and an absolute increase of ≥ 0.5 × 10^9/L
  ◦ For pre-treatment ANC ≤ 0.5 × 10^9/L , neutrophils with ≥ 100% and an absolute increase of ≥ 0.5 × 10^9/L

No response/stable disease

• Does not meet the criteria for at least HI but no evidence of disease progression to AML

Progression from Hematologic Improvement

• Transfusion dependence defined by history of at least 2 units of red blood cell transfusions in the past month for a hemoglobin level < 8.5 g/dL without other explanation
• Reduction in hemoglobin by ≥ 1.5 g/dL
• ≥ 50% reduction from maximum response levels in granulocytes or platelets
Note: if the above criteria for progression have been met, but a hematologic improvement was not previously achieved, report “No Response (NR) / Stable Disease (SD)”.

Relapse from CR

- Reappearance of bone marrow disease, including blasts, monocytic blast equivalents, or fibrosis
- New extramedullary disease, including new or reappearance of splenomegaly, hepatomegaly, skin lesions, etc.


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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Manual Section</th>
<th>Add/ Remove/ Modify</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/7/17</td>
<td>MDS/MPN Response Criteria</td>
<td>Add</td>
<td>Added following bullet to CR criteria for Myelofibrosis: • Myelofibrosis absent or ≤ grade 1 fibrosis (mild reticulin fibrosis)</td>
</tr>
<tr>
<td>9/27/15</td>
<td>MDS/MPN Response Criteria</td>
<td>Modify</td>
<td>Added language to NR/SD criteria: Does not meet the criteria for at least HI, but no evidence of disease progression to AML.</td>
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<td>9/27/15</td>
<td>MDS/MPN Response Criteria</td>
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<td>Added MPN criteria</td>
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<tr>
<td>6/26/15</td>
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<td>Modify</td>
<td>Edited Progression to AML text to read: ≥ 20% blasts in the blood or bone marrow</td>
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<td>6/5/15</td>
<td>MDS/MPN Response Criteria</td>
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<td>Changed the following text in HI-P:</td>
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<td>Criteria</td>
<td>Date</td>
<td>Change Type</td>
<td>Notes</td>
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<tr>
<td>For pre-transplant treatment platelet count of $&gt; 20 \times 10^9$, platelet absolute increase of $\geq 30 \times 10^9$</td>
<td>5/22/15</td>
<td>Add</td>
<td>Added the following text to CR: In some cases, there may not be a four-week interval between completion of therapy and the pre-transplant disease assessment. In this case, CR should still be reported as the status at transplant since it represents the &quot;best assessment&quot; prior to HCT. This is an exception to the criteria that CR be durable beyond four weeks; the pre-transplant disease status should not be changed based on early relapse or disease assessment post-transplant.</td>
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<tr>
<td>For pre-transplant treatment platelet count of $&lt; 20 \times 10^9$, platelet absolute increase of $\geq 20 \times 10^9$ and $\geq 100%$ increase from pre-treatment level</td>
<td>6/24/16</td>
<td>Modify</td>
<td>Added language to note beneath Progression from Hematologic Improvement for MDS and MPN Response Criteria: If the above criteria for progression have been met, but a hematologic improvement was not previously achieved, report &quot;No Response (NR) / Stable Disease (SD)&quot;.</td>
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<tr>
<td>Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:</td>
<td>6/24/16</td>
<td>Add</td>
<td>Added language to MPN Disease Status Criteria, Hematologic Improvement: Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:</td>
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*Last modified: 2018/10/18*