

## LEUKEMIA TREATMENT REGIMENS: Acute Myeloid Leukemia (AML) (Part 1 of 3)

The selection, dosing, and administration of anticancer agents and the management of associated toxicities are complex. Drug dose modifications and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and because of individual patient variability, prior treatment, and comorbidities. Thus, the optimal delivery of anticancer agents requires a healthcare delivery team experienced in the use of such agents and the management of associated toxicities in patients with cancer. The cancer treatment regimens below may include both FDA-approved and unapproved uses/regimens and are provided as references only to the latest treatment strategies. Clinicians must choose and verify treatment options based on the individual patient.

### Induction Therapy

<p><b>Age &lt;60 years</b></p>	<p><b>Days 1-3:</b> An anthracycline (daunorubicin 60–90mg/m<sup>2</sup> continuous IV, <b>OR</b> idarubicin 12mg/m<sup>2</sup>), <b>plus</b>  <b>Days 1-7:</b> Cytarabine 100–200mg/m<sup>2</sup> continuous IV.<sup>1,2</sup>  <b>OR</b>  <b>Days 1-3:</b> An anthracycline (daunorubicin 45–60mg/m<sup>2</sup> continuous IV, <b>OR</b> idarubicin 12mg/m<sup>2</sup>), <b>plus</b>  <b>Days 1-6:</b> High-dose cytarabine 2g/m<sup>2</sup> IV every 12 hrs.<sup>1,3,4</sup>  <b>OR</b>  <b>Days 1-3:</b> An anthracycline (daunorubicin 45–60mg/m<sup>2</sup> continuous IV, <b>OR</b> idarubicin 12mg/m<sup>2</sup>), <b>plus</b>  <b>Days 1-4:</b> High-dose cytarabine 3g/m<sup>2</sup> IV every 12 hrs.<sup>1,5</sup>  <b>OR</b>  Matched sibling or alternative donor HSCT.<sup>1</sup>  <b>OR</b>  Clinical Trial.</p>
<p><b>Age ≥60 years</b><sup>1,6</sup>  Performance Status 0–2  Favorable cytogenetic markers without prior MDS/Therapy-related AML</p>	<p><b>Days 1-3:</b> An anthracycline (daunorubicin 45–60mg/m<sup>2</sup> continuous IV, <b>OR</b> idarubicin 12mg/m<sup>2</sup> IV, <b>OR</b> mitoxantrone 12mg/m<sup>2</sup> IV), <b>plus</b>  <b>Days 1-7:</b> Cytarabine 100–200mg/m<sup>2</sup> continuous IV.<sup>1,7</sup>  <b>OR</b>  <u>Low-intensity therapy</u>  <b>Days 1-10:</b> Cytarabine 20mg SC twice daily.<sup>1,8</sup> <b>OR</b>  <b>Days 1-7:</b> 5-azacytidine 75mg/m<sup>2</sup> IV every 28 days.<sup>1,9</sup> <b>OR</b>  <b>Days 1-5:</b> Decitabine 20mg/m<sup>2</sup> IV for a 4-week cycle.<sup>1,10</sup>  <b>OR</b>  <u>Intermediate-intensity therapy</u>  <b>Days 1-5:</b> Clofarabine 30mg/m<sup>2</sup> IV over 1 hr.<sup>1,11</sup>  Clinical Trial.</p>
<p><b>Age ≥60 years</b>  Performance Status 0–2  Therapy-related AML/prior MDS or unfavorable cytogenetic/molecular markers</p>	<p><b>Days 1-3:</b> An anthracycline (daunorubicin 45–60mg/m<sup>2</sup> continuous IV, <b>OR</b> idarubicin 12mg/m<sup>2</sup> IV, <b>OR</b> mitoxantrone 12mg/m<sup>2</sup> IV), <b>plus</b>  <b>Days 1-7:</b> Cytarabine 100–200mg/m<sup>2</sup> continuous IV.  <b>OR</b>  <u>Low-intensity therapy</u>  <b>Days 1-7:</b> 5-azacytidine 75mg/m<sup>2</sup> IV every 28 days.<sup>1,9</sup> <b>OR</b>  <b>Days 1-5:</b> Decitabine 20mg/m<sup>2</sup> IV for a 4-week cycle.<sup>1,10</sup>  <b>OR</b>  <u>Intermediate-intensity therapy</u>  <b>Days 1-5:</b> Clofarabine 30mg/m<sup>2</sup> IV over 1 hr.<sup>1,11</sup>  Clinical Trial.</p>
<p><b>Age ≥60 years</b>  Performance Status &gt;2</p>	<p><u>Low-intensity therapy</u>  <b>Days 1-10:</b> Cytarabine 20mg SC twice daily.<sup>1,8</sup> <b>OR</b>  <b>Days 1-7:</b> 5-azacytidine 75mg/m<sup>2</sup> IV every 28 days.<sup>1,9</sup> <b>OR</b>  <b>Days 1-5:</b> Decitabine 20mg/m<sup>2</sup> IV for a 4-week cycle.<sup>1,10</sup>  <b>OR</b>  <u>Best supportive care</u>  Hydroxyurea sufficient to maintain target white blood cell count &lt;10,000/mcL.<sup>1,8</sup> <b>OR</b>  Transfusion support.  <b>OR</b>  Clinical Trial.</p>
<p><b>Age ≥60 years</b>  Performance Status 0–3  Significant comorbidities</p>	<p><u>Low-intensity therapy</u>  <b>Days 1-10:</b> Cytarabine 20mg SC twice daily.<sup>1,8</sup> <b>OR</b>  <b>Days 1-7:</b> 5-azacytidine 75mg/m<sup>2</sup> IV every 28 days.<sup>1,9</sup> <b>OR</b>  <b>Days 1-5:</b> Decitabine 20mg/m<sup>2</sup> IV for a 4-week cycle.<sup>1,10</sup>  <b>OR</b>  <u>Best supportive care</u>  Hydroxyurea sufficient to maintain target white blood cell count &lt;10,000/mcL.<sup>1,8</sup> <b>OR</b>  Transfusion support.</p>

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## LEUKEMIA TREATMENT REGIMENS: Acute Myeloid Leukemia (AML) (Part 2 of 3)

### Consolidation Therapy

<b>Age &lt;60 years<sup>1</sup></b> Induction Failure	<p>Clinical Trial.</p> <p style="text-align: center;"><b>OR</b></p> <p>Matched sibling or alternative donor HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p>High-dose cytarabine (if not previously used as treatment for persistent disease at day 15) ± anthracycline (daunorubicin or idarubicin), if a clinical trial is not available while awaiting identification of a donor.</p> <p style="text-align: center;"><b>OR</b></p> <p>Best supportive care.</p>
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### Post-Remission Therapy

<b>Age &lt;60 years</b> Better-risk cytogenetics or molecular abnormalities	<p><b>Days 1, 3, and 5 for 3–4 cycles:</b> High-dose cytarabine 3g/m<sup>2</sup> IV every 12 hrs.<sup>1,12,13</sup></p> <p style="text-align: center;"><b>OR</b></p> <p>1–2 cycles of high-dose cytarabine-based consolidation followed by autologous HSCT.<sup>1</sup></p> <p style="text-align: center;"><b>OR</b></p> <p>Clinical Trial.</p>
<b>Age &lt;60 years<sup>1</sup></b> Intermediate-risk cytogenetics or molecular abnormalities	<p>Matched sibling or unrelated donor HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p><b>Days 1, 3, and 5 for 3–4 cycles:</b> High-dose cytarabine 1.5–3g/m<sup>2</sup> IV every 12 hrs.</p> <p>1–2 cycles of high-dose cytarabine-based consolidation followed by autologous HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p>Clinical Trial.</p>
<b>Age &lt;60 years<sup>1</sup></b> Treatment-related disease or poor-risk cytogenetics or molecular abnormalities	<p>Clinical Trial.</p> <p style="text-align: center;"><b>OR</b></p> <p>Matched sibling or alternative donor HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p>1–2 cycles of high-dose cytarabine-based consolidation followed by autologous HSCT if no allogeneic transplant option is available.</p>
<b>Age ≥60 years<sup>1</sup></b> Complete Response	<p>Clinical Trial.</p> <p style="text-align: center;"><b>OR</b></p> <p>Reduced-intensity HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p>Cytarabine 100–200mg/m<sup>2</sup> IV for 5–7 days for 1–2 cycles, <b>plus</b> Anthracycline (idarubicin or daunorubicin).</p> <p style="text-align: center;"><b>OR</b></p> <p>Cytarabine 1–1.5g/m<sup>2</sup> IV for 4–6 doses for 1–2 cycles for patients with good performance status, normal renal function, better-risk, or normal karyotype with favorable molecular markers.</p> <p style="text-align: center;"><b>OR</b></p> <p>Continue low-intensity regimens (5-azacytidine, decitabine) every 4–6 weeks until progression.</p>

### Salvage Therapy

<b>Age &lt;60 years<sup>1</sup></b> Early Relapse (<12 months)	<p>Clinical Trial (strongly preferred).</p> <p style="text-align: center;"><b>OR</b></p> <p>*Salvage chemotherapy followed by matched sibling or alternative donor HSCT.</p>
<b>Age &lt;60 years<sup>1</sup></b> Late Relapse (>12 months)	<p>Clinical Trial (strongly preferred).</p> <p style="text-align: center;"><b>OR</b></p> <p>*Salvage chemotherapy followed by matched sibling or alternative donor HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p>Repeat initial successful induction regimen.</p>
<b>Age ≥60 years<sup>1</sup></b> Early Relapse (<12 months)	<p>Clinical Trial (strongly preferred).</p> <p style="text-align: center;"><b>OR</b></p> <p>Best supportive care.</p> <p style="text-align: center;"><b>OR</b></p> <p>*Salvage chemotherapy followed by matched sibling or alternative donor HSCT.</p>
<b>Age ≥60 years<sup>1</sup></b> Late Relapse (>12 months)	<p>Clinical Trial (strongly preferred).</p> <p style="text-align: center;"><b>OR</b></p> <p>Treatment with initial successful regimen.</p> <p style="text-align: center;"><b>OR</b></p> <p>*Salvage chemotherapy followed by matched sibling or alternative donor HSCT.</p> <p style="text-align: center;"><b>OR</b></p> <p>Best supportive care.</p>

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## LEUKEMIA TREATMENT REGIMENS: Acute Myeloid Leukemia (AML) (Part 3 of 3)

### Salvage Therapy (continued)

#### \*Salvage Chemotherapy Options<sup>1</sup>

**Days 1-5:** Cladribine 5mg/m<sup>2</sup> IV, **plus**  
**Days 1-5:** Cytarabine 2g/m<sup>2</sup> IV, **plus**  
**Days 0-5:** G-CSF 300mcg SC  
**Days 1-3:** Mitoxantrone 10mg/m<sup>2</sup> IV, **OR** idarubicin.  
**OR**  
 High-dose cytarabine (if not previously used in treatment) ± anthracycline.  
**OR**  
**Days 1-5:** Fludarabine 30mg/m<sup>2</sup> IV over 0.5 hrs, **plus**  
**Days 1-5:** Cytarabine 2g/m<sup>2</sup> IV over 4 hrs, **plus**  
**Days 0 to polymorphonuclear recovery (>0.5 x 10<sup>9</sup>/L):** G-CSF 5mcg/kg or 300mcg/m<sup>2</sup>.  
 ±  
**Days 1-3:** Idarubicin 10mg/m<sup>2</sup> IV.<sup>1,15,16</sup>  
**OR**  
**Days 1-6:** Etoposide 80mg/m<sup>2</sup> IV over 1 hr, **plus**  
**Days 1-6:** Cytarabine 1g/m<sup>2</sup> IV over 6 hrs.  
 ±  
**Days 1-6:** Mitoxantrone 6mg/m<sup>2</sup> IV bolus.<sup>1,17</sup>  
**OR**  
**Days 1-5:** Clofarabine 25mg/m<sup>2</sup> IV, **plus**  
**Days 1-5:** Cytarabine 2g/m<sup>2</sup> IV, **plus**  
**Days 0 to neutrophil recovery:** G-CSF 5mcg/kg/day.<sup>1,18</sup>

### References

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