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

#### Clinical Trials:
The National Comprehensive Cancer Network (NCCN) recommends cancer patient participation in clinical trials as the gold standard for treatment.

Cancer therapy selection, dosing, administration, and the management of related adverse events can be a complex process that should be handled by an experienced healthcare team. Clinicians must choose and verify treatment options based on the individual patient; drug dose modifications and supportive care interventions should be administered accordingly. The cancer treatment regimens below may include both U.S. Food and Drug Administration-approved and unapproved indications/regimens. These regimens are only provided to supplement the latest treatment strategies.

These Guidelines are a work in progress that may be refined as often as new significant data becomes available. The NCCN Guidelines® are a consensus statement of its authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult any NCCN Guidelines® is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment. The NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

### Induction Therapy

**Note:** All recommendations are Category 2A unless otherwise indicated. The NCCN believes the best option for any patient with cancer is in a clinical trial and strongly encourages this option for all patients.

#### PATIENT CRITERIA

<table>
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<tr>
<th>REGIMEN AND DOSING</th>
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| **Age <60 years**

Days 1–3: An anthracycline (daunorubicin 60–90mg/m² IV, OR idarubicin 12mg/m³),

Days 1–7: Cytarabine 100–200mg/m² continuous IV (Category 1).

**OR**

Days 1–3: Daunorubicin 60mg/m² IV,

Days 1–7: Cytarabine 200mg/m² continuous IV,

Days 1–5: Cladribine 5 mg/m².

**OR**

Days 1–3: An anthracycline (daunorubicin 60mg/m² IV, OR idarubicin 12mg/m³),

Days 1–6: High-dose cytarabine 2g/m² IV every 12 hours, **OR**

Days 1–4: High-dose cytarabine 3g/m² IV every 12 hours (Category 1 for patients ≤45 years, category 2B for other age groups).

**OR**

Days 1–7: SC granulocyte-colony stimulating factor (G-CSF),

Days 2–6: Fludarabine 30mg/m² plus high-dose cytarabine 2g/m² over 4 hours after starting fludarabine on days 2–6,

Days 4–6: Idarubicin 8mg/m² IV (Category 2B).

**Age ≥60 years**

De novo AML without unfavorable cytogenetics or molecular markers; no antecedent hematologic disorder; and no therapy-related AML

Days 1–3: An anthracycline (daunorubicin 60–90mg/m² IV, OR idarubicin 12mg/m³ IV, OR mitoxantrone 12mg/m³ IV),

Days 1–7: Cytarabine 100–200mg/m² continuous IV.

**Age ≥60 years**

Unfavorable cytogenetics or molecular markers; antecedent hematologic disorder; therapy-related AML

**Lower-intensity therapy**

Days 1–7: 5-azacytidine 75mg/m² IV every 28 days, **OR**

Days 1–5: Decitabine 20mg/m² IV for a 4-week cycle.

**OR**

Days 1–3: An anthracycline (daunorubicin 60–90mg/m³ IV, OR idarubicin 12mg/m³ IV, OR mitoxantrone 12mg/m³ IV),

Days 1–7: Cytarabine 100–200mg/m² continuous IV.

**OR**

Clofarabine with or without standard-dose cytarabine (Category 3).

**Age ≥60 years**

Not a candidate for intensive therapy or declines intensive therapy

**Lower-intensity therapy**

Days 1–7: 5-azacytidine 75mg/m² IV every 28 days, **OR**

Days 1–7: 5-azacytidine 75mg/m² IV every 28 days, **OR**

Days 1–5: Decitabine 20mg/m² IV every 28 days (5-azacytidine or decitabine preferred).

**OR**

Best supportive care (hydroxyurea, transfusion support).

**Post-Remission Therapy**

**Age <60 years**

Core binding factor cytogenetic translocations without KIT mutation or favorable-risk molecular abnormalities

Days 1, 3, and 5: High-dose cytarabine 3g/m² IV every 12 hours for 3–4 cycles (Category 1).

**Age ≥60 years**

Complete Response After Previous Intensive Therapy

Cytarabine 100–200mg/m² IV for 5–7 days for 1–2 cycles, ± anthracycline (idarubicin or daunorubicin).

**OR**

Cytarabine 1–1.5g/m² 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.

**OR**

Maintenance hypomethylating regimen (5-azacytidine, decitabine) every 4–6 weeks until progression (if patient received hypomethylating agents in induction).

**OR**

Reduced-intensity HCT.

**OR**

Observation.

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

### Post-Remission Therapy (continued)

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<tr>
<th>PATIENT CRITERIA</th>
<th>REGIMEN AND DOSING</th>
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<td>Age ≥60 years</td>
<td>Reduced-intensity HCT (preferably in clinical trial). OR Best supportive care.</td>
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</table>

| Age ≥60 years | Reduced-intensity HCT. OR Continue hypomethylating regimens (5-azacytidine, decitabine) every 4–6 weeks until progression. |

| Age ≥60 years | Best supportive care. |

### Therapy for Relapse or Refractory Disease

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<tr>
<th>Therapy for Relapse or Refractory Disease</th>
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<tr>
<td>Age &lt;60 years Early Relapse (&lt;12 months)</td>
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| Age <60 years Late Relapse (≥12 months) | Chemotherapy* followed by matched sibling or alternative donor HCT. OR Repeat initial successful induction regimen. |

| Age ≥60 years Early Relapse (<12 months) | Chemotherapy* followed by matched sibling or alternative donor HCT. OR Best supportive care. |

| Age ≥60 years Late Relapse (≥12 months) | Repeat initial successful induction regimen. OR Chemotherapy* followed by matched sibling or alternative donor HCT. OR Best supportive care. |

### *Chemotherapy Options*[^8-10,14-19]

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<th>Aggressive therapy for appropriate patients:</th>
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<tr>
<td>Days 1-5: Cladribine 5mg/m² IV, Days 1-5: Cytarabine 2g/m² IV, Days 0-5: G-CSF 300mcg SC, ± Days 1-3: Mitoxantrone 10mg/m² IV, OR idarubicin 10mg/m² IV. OR High-dose cytarabine (if not previously used in treatment) ± anthracycline. OR Days 1-5: Fludarabine 30mg/m² IV over 0.5 hours, Days 1-5: Cytarabine 2g/m² IV over 4 hours, Days 0 to polymorphonuclear recovery (&gt;0.5 x 10⁹/L): G-CSF 5mcg/kg or 300mcg/m². (G-CSF may also start on Day +6 until engraftment.) ± Days 1-3: Idarubicin 10mg/m² IV. OR Days 1-6: Etoposide 80mg/m² IV over 1 hour, Days 1-6: Cytarabine 1g/m² IV over 6 hours. ± Days 1-6: Mitoxantrone 6mg/m² IV bolus. OR Days 1-5: Clofarabine 22.5mg/m²–25mg/m² IV, ± Days 2-6: Cytarabine 0.75g/m²–2g/m² IV, Days 0 to neutrophil recovery: G-CSF 5mcg/kg/day, ± Days 1-3: Idarubicin 6-8 mg/m² IV.</td>
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<th>Less aggressive therapy:</th>
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<td>Hypomethylating agents (5-azacytidine or decitabine) OR Low-dose cytarabine (Category 2B).</td>
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### Therapy for patients with FLT3-ITD disease:

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<tr>
<td>Days 1-7: 5-azacytidine 75mg/m² IV, + Sorafenib 400 mg orally twice daily continuously. OR Decitabine + sorafenib</td>
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### References


