

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

Clinical Trials: The 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 National Comprehensive Cancer Network 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 Therapy¹

Note: All recommendations are Category 2A unless otherwise indicated.

REGIMEN	DOSING
Age <60 years ²⁻⁵	Days 1-3: An anthracycline (daunorubicin 90mg/m ² continuous IV, OR idarubicin 12mg/m ²), Days 1-7: Cytarabine 100-200mg/m ² continuous IV (Category 1). OR Days 1-3: Daunorubicin 60mg/m ² continuous IV, Days 1-7: Cytarabine 200mg/m ² continuous IV, Days 1-5: Cladribine 5 mg/m ² (Category 1). OR Days 1-3: An anthracycline (daunorubicin 60mg/m ² continuous IV, OR idarubicin 12mg/m ²), Days 1-6: High-dose cytarabine 2g/m ² IV every 12 hours, OR Days 1-4: High-dose cytarabine 3g/m ² IV every 12 hours (Category 2B).
Age ≥60 years ⁶⁻¹⁰ Performance Status 0-2 Favorable cytogenetic markers without prior MDS/Therapy-related AML	Days 1-3: An anthracycline (daunorubicin 45-90mg/m ² continuous IV, OR idarubicin 12mg/m ² IV (preferred), OR mitoxantrone 12mg/m ² IV), Days 1-7: Cytarabine 100-200mg/m ² continuous IV. OR Low-intensity therapy Days 1-10: Cytarabine 20mg SC twice daily, OR Days 1-7: 5-azacytidine 75mg/m ² IV every 28 days, OR Days 1-5: Decitabine 20mg/m ² IV for a 4-week cycle.
Age ≥60 years ^{6,7,9,10} Performance Status 0-2 Unfavorable cytogenetic markers with prior MDS/Therapy-related AML	Low-intensity therapy Days 1-7: 5-azacytidine 75mg/m ² IV every 28 days, OR Days 1-5: Decitabine 20mg/m ² IV for a 4-week cycle. OR Days 1-3: An anthracycline (daunorubicin 45-60mg/m ² continuous IV, OR idarubicin 12mg/m ² IV (preferred), OR mitoxantrone 12mg/m ² IV), Days 1-7: Cytarabine 100-200mg/m ² continuous IV.
Age ≥60 years ⁸⁻¹¹ Performance Status >2 or 0-3 with significant comorbidities	Low-intensity therapy Days 1-10: Cytarabine 20mg SC twice daily, OR Days 1-7: 5-azacytidine 75mg/m ² IV every 28 days, OR Days 1-5: Decitabine 20mg/m ² IV every 28 days. OR Hydroxyurea 10-70mg/kg/day orally in divided doses.
Post-Remission Therapy ¹	
Age <60 years ^{12,13} Better-risk cytogenetics or molecular abnormalities	Days 1, 3, and 5: High-dose cytarabine 3g/m ² IV every 12 hours for 3-4 cycles (Category 1). OR 1-2 cycles of high-dose cytarabine-based consolidation followed by autologous hematopoietic stem cell transplant (HSCT) (Category 2B).
Age <60 years ^{12,13} Intermediate-risk cytogenetics or molecular abnormalities	Days 1, 3, and 5: High-dose cytarabine 1.5-3g/m ² IV every 12 hours for 3-4 cycles. OR Matched sibling or unrelated donor HSCT.

continued

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Post-Remission Therapy¹ (continued)

REGIMEN	DOSING
Age <60 years Treatment-related disease or poor-risk cytogenetics or molecular abnormalities	Matched sibling or unrelated donor HSCT.
Age ≥60 years Complete Response	Cytarabine 100-200mg/m ² IV for 5-7 days for 1-2 cycles, ± anthracycline (idarubicin or daunorubicin). OR Cytarabine 1-1.5g/m ² IV for 4-6 doses for 1-2 cycles for patients. OR Continue low-intensity regimens (5-azacytidine, decitabine) every 4-6 weeks until progression. OR Reduced intensity HSCT.
Age ≥60 years Induction Failure	Reduced-intensity HSCT in context of clinical trial OR Best supportive care

Salvage Therapy¹

Age <60 years Early Relapse (<12 months)	Salvage chemotherapy* followed by matched sibling or alternative donor HSCT.
Age <60 years Late Relapse (>12 months)	Salvage chemotherapy* followed by matched sibling or alternative donor HSCT. OR Repeat initial successful induction regimen.
Age ≥60 years Early Relapse (<12 months)	Salvage chemotherapy* followed by matched sibling or alternative donor HSCT. OR Best supportive care
Age ≥60 years Late Relapse (>12 months)	Repeat initial successful regimen. OR Salvage chemotherapy* followed by matched sibling or alternative donor HSCT. OR Best supportive care

*Salvage Chemotherapy Options¹⁴⁻¹⁸

Days 1-5: Cladribine 5mg/m² IV,
Days 1-5: Cytarabine 2g/m² IV,
Days 0-5: Granulocyte-colony stimulating factor (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 (>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 25mg/m² IV,
Days 2-6: Cytarabine 2g/m² IV,
Days 0 to neutrophil recovery: G-CSF 5mcg/kg/day.

continued

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