

LEUKEMIA TREATMENT REGIMENS: Chronic Myeloid Leukemia (CML) (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.

Primary Treatment¹

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

REGIMEN	DOSING
Ph positive or BCR-ABL positive²⁻⁹	Imatinib 400mg orally daily (Category 1) OR Nilotinib 300mg orally twice daily (Category 1) OR Dasatinib 100mg orally daily (Category 1).

3 Month Evaluation

BCR-ABL1/ABL1<10% (IS) or PCyR²⁻⁹	Continue current regimen.
If response of BCR-ABL1 transcripts >10% (IS) or less than PCyR on bone marrow cytogenetics⁹⁻¹² Evaluate patient compliance and drug-drug interactions, consider mutational analysis and bone marrow cytogenetics	Primary Treatment with Imatinib Change Therapy to alternate TKI OR Imatinib dose may be increased to a maximum of 800 mg, if tolerated and evaluate for hematopoietic stem cell transplantation (HSCT) depending on response to tyrosine kinase inhibitor (TKI) therapy Primary Treatment with Nilotinib or Dasatinib Continue same dose of nilotinib or dasatinib OR Change Therapy to alternate TKI (other than imatinib) and evaluate for HSCT depending on response to TKI therapy

6 Month Evaluation¹

BCR-ABL1/ABL1<10% (IS) or PCyR²⁻⁹	Continue current regimen.
If response of BCR-ABL1 transcripts >10% (IS) or less than PCyR on bone marrow cytogenetics¹³ Evaluate patient compliance and drug-drug interactions, consider mutational analysis and bone marrow cytogenetics	Change Therapy to alternate TKI (other than imatinib) and evaluate for HSCT depending on response to TKI therapy

12 Month Evaluation¹

Complete cytogenetic response²⁻⁹	Continue current regimen.
Partial cytogenetic response¹⁰ Evaluate patient compliance and drug-drug interactions, consider mutational analysis and bone marrow cytogenetics	Change therapy to alternate TKI (other than imatinib) OR Continue same dose of TKI OR Increase dose of imatinib to a maximum dose of 800 mg, as tolerated (if not candidate for alternate TKI or omacetaxine)
Minor or no cytogenetic response¹⁰ Evaluate patient compliance and drug-drug interactions, consider mutational analysis	Change therapy to alternate TKI (preferred) (other than imatinib) and evaluate for HSCT depending on response to TKI

continued

LEUKEMIA TREATMENT REGIMENS: Chronic Myeloid Leukemia (CML) (Part 2 of 3)

12 Month Evaluation¹ (continued)

REGIMEN	DOSING
Cytogenetic relapse¹⁰ Evaluate patient compliance and drug-drug interactions, mutational analysis	Change therapy to alternate TKI (preferred) (other than imatinib) OR Increase dose of imatinib to a maximum dose of 800 mg, as tolerated (if not candidate for alternate TKI or omacetaxine) and evaluate for HSCT depending on response to TKI therapy.

18 Month Evaluation¹

Complete cytogenetic²⁻⁹	Continue previous regimen.
Partial cytogenetic response¹⁴ Evaluate patient compliance and drug-drug interactions, mutational analysis	Change therapy to alternate TKI (other than imatinib) and repeat bone marrow evaluation at 3 months to document Complete Cytogenetic Response (CCyR) AND Evaluation for HSCT depending on response to TKI therapy.
Cytogenetic relapse¹⁴ Evaluate patient compliance and drug-drug interactions, mutational analysis	Change therapy to alternate TKI (other than imatinib) and repeat bone marrow evaluation at 3 months to document Complete Cytogenetic Response (CCyR) AND Evaluation for HSCT depending on response to TKI therapy.

Advanced Phase¹

Accelerated phase¹⁵⁻³¹	Imatinib 600mg orally daily OR Dasatinib 140mg orally daily (70mg twice daily) OR Nilotinib 400mg orally twice daily OR Bosutinib 500mg orally daily OR Omacetaxine 1.25mg/m ² SC twice daily on days 1–14 cycled every 28 days until hematologic response, followed by omacetaxine 1.25mg/m ² SC twice daily on days 1–7 cycled every 28 days until disease progression or unacceptable toxicity AND Consider HSCT based on response.
Blast phase—lymphoid¹⁵⁻³¹	ALL-type induction chemotherapy, plus TKI followed by HSCT, if feasible OR TKI followed by HSCT, if feasible.
Blast phase—myeloid¹⁵⁻³¹	AML-type induction chemotherapy, plus TKI followed by HSCT, if feasible. OR TKI followed by HSCT, if feasible.

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LEUKEMIA TREATMENT REGIMENS: Chronic Myeloid Leukemia (CML) (Part 3 of 3)

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