

How does Mylotarg fit into an ESMO treatment guideline for newly diagnosed Acute Myeloid Leukemia patients?

Adult AML eligible for standard Chemo Therapy (ChT)

Patients should be encouraged to participate in clinical trials whenever possible.

The final decision concerning the role of intensive ChT is taken after careful consultation between an experienced clinician and the patient.

Recommended treatment for:

Patient subgroup:	Induction		Consolidation		
	1	2	1	2	3
1 Core Binding Factor AML	7 days cytarabine and 3 days daunorubicin (7+3) ■ If blasts are CD33-positive: gemtuzumab ozogamicin	7 days cytarabine and 3 days daunorubicin (7+3)	CR ●● intermediate-dose cytarabine (IDAC) ■ If patient <60-65: gemtuzumab ozogamicin ⊕ Alternative: autoHCT	●● intermediate-dose cytarabine (IDAC) ■ If patient <60-65: gemtuzumab ozogamicin	●● intermediate-dose cytarabine (IDAC)
2 Therapy-related AML or AML with Myelodysplasia related cytogenetic changes (AML-MRC) + older than 60 years	●● cytarabine and liposomal daunorubicin (CPX-351)	●● cytarabine and liposomal daunorubicin (CPX-351)	CR ●● cytarabine and liposomal daunorubicin (CPX-351)	●● cytarabine and liposomal daunorubicin (CPX-351)	
3 FLT3-ITD+ or FLT3-TKD+	7 days cytarabine and 3 days daunorubicin (7+3) ● midostaurin	7 days cytarabine and 3 days daunorubicin (7+3) ● midostaurin	CR ●● intermediate-dose cytarabine (IDAC) ● midostaurin	●● intermediate-dose cytarabine (IDAC) ● midostaurin	●● intermediate-dose cytarabine (IDAC) ● midostaurin
4 ELN1 (Favourable risk profile)	7 days cytarabine and 3 days daunorubicin (7+3) ■ If blasts are CD33-positive: gemtuzumab ozogamicin	7 days cytarabine and 3 days daunorubicin (7+3)	CR ●● intermediate-dose cytarabine (IDAC) ■ If patient <60-65: gemtuzumab ozogamicin ⊕ Alternative: autoHCT	●● intermediate-dose cytarabine (IDAC) ■ If patient <60-65: gemtuzumab ozogamicin ⊕ Alternative: autoHCT	●● intermediate-dose cytarabine (IDAC)
5 ELN 2 (Intermediate risk profile)	7 days cytarabine and 3 days daunorubicin (7+3) ■ If blasts are CD33-positive: gemtuzumab ozogamicin	7 days cytarabine and 3 days daunorubicin (7+3)	CR ●● intermediate-dose cytarabine (IDAC) ■ If patient <60-65: gemtuzumab ozogamicin	⊕ alloHCT (donor availability) ●● If not feasible: intermediate-dose cytarabine (IDAC) ⊕ or autoHCT	●● If no alloHCT: intermediate-dose cytarabine (IDAC)
6 ELN 3 (Adverse risk profile)	7 days cytarabine and 3 days daunorubicin (7+3) optional: + cladribine or: fludarabine	7 days cytarabine and 3 days daunorubicin (7+3) optional: + cladribine or: fludarabine	CR ⊕ alloHCT (donor availability) If alloHCT not possible: Consider MACE/MIDAC.	●● If alloHCT is delayed: 1-2x intermediate-dose cytarabine (IDAC)	●● If no alloHCT: intermediate-dose cytarabine (IDAC)

CR: Complete remission

Diagram based on:
M. Heuser, Y. Ofran, N. Boissel, et al. on behalf of the ESMO Guidelines Committee (2020) *Acute myeloid leukaemia in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up*. Annals of oncology, (31)6, 697-712, June 01, 2020
<https://doi.org/10.1016/j.annonc.2020.02.018>

For FLT3-ITD or FLT3-TKD patients, the use of midostaurin is optional as a maintenance treatment after the Consolidation phase.

AlloHCT should be considered for all patients after the Consolidation phase. For ELN2 and ELN3 patients, alloHCT could be considered during the Consolidation phase.