

Active substances set

Search phrase: Acute myeloid leukemia

Below you will find a list of active substances registered by the European Medical Agency (EMA) in the last 15 years, recommended by the European Society of Clinical Oncology (ESMO) and their reimbursement status in the country.

Acute myeloid leukemia

Glasdegib

Glasdegib is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukaemia (AML) in adult patients who are not candidates for standard induction chemotherapy.

 **NO REIMBURSEMENT**
 **ESMO**

Decitabine

Decitabine is indicated for the treatment of adult patients with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

 **REIMBURSEMENT WITH RESTRICTIONS**
 **ESMO**

Midostaurin

Midostaurin is indicated in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by Midostaurin single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive.

 **REIMBURSEMENT WITH RESTRICTIONS**
 **ESMO**

Gemtuzumab ozogamicin

Gemtuzumab Ozogamicin is indicated for combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of patients aged 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL).

 **REIMBURSEMENT WITH RESTRICTIONS**
 **ESMO**

**Daunorubicin /
cytarabine**

Daunorubicin / Cytarabine is indicated for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

-  **REIMBURSEMENT WITH RESTRICTIONS**
-  **ESMO**

Gilteritinib

Gilteritinib is indicated as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation.

-  **REIMBURSEMENT WITH RESTRICTIONS**
-  **ESMO**

Venetoclax

Venetoclax in combination with a hypomethylating agent is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.

-  **REIMBURSEMENT WITH RESTRICTIONS**
-  **ESMO**

Quizartinib

Quizartinib is indicated in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by VANFLYTA single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) that is FLT3-ITD positive.

-  **REIMBURSEMENT WITH RESTRICTIONS**
-  **ESMO**

Ivosidenib

Ivosidenib in combination with azacitidine is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy .

-  **FULL REIMBURSEMENT**
-  **ESMO**