

## 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

#### 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**

#### 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.

 **FULL  
REIMBURSEMENT**

 **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.



**FULL  
REIMBURSEMENT**



**ESMO**