What is acute myeloid leukaemia?
Acute myeloid leukaemia (AML) is a type of cancer of the white blood cells. It starts in the bone marrow but quickly moves into the blood. There are different subtypes of AML. Diagnostic tests that detect abnormalities in the cancer cell’s DNA (cytogenetic testing), can be used to predict how well patients will respond to treatments depending on whether the cancer cells have characteristics described as favourable, intermediate or unfavourable. In many cases of AML the cancer cells have a protein on their surface called CD33.

How does gemtuzumab ozogamicin work?
Gemtuzumab ozogamicin is made up of two active parts: an antibody (a type of protein) that attaches to the CD33 protein on the surface of the cancerous cell and a cytotoxic agent (a substance that is toxic to cells). When the antibody attaches to CD33, the cytotoxic substance is absorbed into the cell which damages the cancer cell’s DNA and kills it. Gemtuzumab ozogamicin is not to be used in patients with a type of AML called acute promyelocytic leukaemia (APL).

What has SMC said?
SMC has accepted gemtuzumab ozogamicin for restricted use, when used together with two chemotherapy medicines (daunorubicin and cytarabine), for the treatment of patients (aged 15 years and over) with a new diagnosis of AML that is CD33 positive, who have not received other treatment. This acceptance is limited to where cytogenetic tests show that the patient has favourable or intermediate characteristics or where cytogenetic test results are not yet available.

Why has SMC said this?
SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).
SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland. When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, applying extra flexibility because gemtuzumab ozogamicin is a medicine for a rare, end of life condition, SMC was able to accept it a possible treatment within NHS Scotland.

**What does SMC’s decision mean for me?**

If your healthcare professional thinks that gemtuzumab ozogamicin, for use as described above is the right medicine for you, you should be able to have the treatment on the NHS in Scotland. For further information see:

Medicines in Scotland: What’s the right treatment for me? 
[www.healthcareimprovementscotland.org/medicinesbooklet.aspx](http://www.healthcareimprovementscotland.org/medicinesbooklet.aspx)

**More information**

The organisations below can provide more information and support for people with AML and their families. SMC is not responsible for the content of any information provided by external organisations.

**Leukaemia CARE**

[https://www.leukaemiacare.org.uk/](https://www.leukaemiacare.org.uk/)  
0808 8010 444

**Bloodwise**

[https://bloodwise.org.uk/](https://bloodwise.org.uk/)  
0808 2080 888

You can find out more about gemtuzumab ozogamicin in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.


**Date advice published:** 8 October 2018

**SMC No:** (SMC2089)