

Putting NICE guidance into practice

Resource impact report: Gemtuzumab ozogamicin for untreated acute myeloid leukaemia (TA545)

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Summary

NICE has recommended gemtuzumab ozogamicin, with daunorubicin and cytarabine, as an option for untreated de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia, in people 15 years and over. The guidance recommends that people start induction therapy when their cytogenetic test results are not yet available (see section 1.1 for further details).

We estimate that:

- 950 people with AML are eligible for treatment with gemtuzumab ozogamicin
- 850 people will have gemtuzumab ozogamicin from year 2020/21 onwards once uptake has reached 90% as shown in table 1
- A further 180 people will have induction treatment only with gemtuzumab ozogamicin from year 2020/21 while awaiting cytogenetic test results to confirm their eligibility for treatment.

Table 1 Estimated number of people in England having gemtuzumab ozogamicin

	2018/19	2019/20	2021/22	2022/23	2023/24
Population having gemtuzumab ozogamicin	40	800	850	850	850
Population having induction treatment only with gemtuzumab ozogamicin	10	170	180	180	180

This report is supported by a local resource impact template because the list price of gemtuzumab ozogamicin has a discount that is commercial in confidence. The discounted price of gemtuzumab ozogamicin can be put into the template and other variables may be amended.

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

1 Gemtuzumab ozogamicin

- 1.1 Gemtuzumab ozogamicin, with daunorubicin and cytarabine, is recommended as an option for untreated de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia, in people 15 years and over, only if:
- they start induction therapy when either the test confirms that the disease has favourable, intermediate or unknown cytogenetics (that is because the test was unsuccessful) or when their cytogenetic test results are not yet available and
 - they start consolidation therapy when their test confirms that the disease has favourable, intermediate or unknown cytogenetics (because the test was unsuccessful) and
 - the company provides gemtuzumab ozogamicin according to the commercial arrangement.
- 1.2 Acute myeloid leukaemia (AML) is a rapidly progressing form of leukaemia. There is a poor prognosis for patients whose disease does not respond to treatment, or whose disease responds then relapses.
- 1.3 AML is currently treated with daunorubicin plus cytarabine. Cytogenetic testing is used to look for specific gene mutations in certain types of leukaemia, which might predict how a person's disease responds to treatment and affect treatment options.
- 1.4 Gemtuzumab ozogamicin will be used in addition to current treatment with daunorubicin plus cytarabine and therefore will be an additional cost.
- 1.5 Intensive treatment for AML is essentially unchanged in 40 years. Although survival has gradually improved this has been largely a result of improvements in supportive care and decision-making about when to have allogeneic stem cell transplant.

2 Resource impact of the guidance

2.1 We estimate that:

- 950 people with AML are eligible for treatment with gemtuzumab ozogamicin each year.
- 850 people will have gemtuzumab ozogamicin from year 2020/21 onwards once uptake has reached 90%.
- A further 180 people will have induction treatment only with gemtuzumab ozogamicin from year 2020/21 while awaiting cytogenic test results to confirm their eligibility for treatment.

2.2 The current treatment and future uptake figure assumptions are based on the company submission and clinical expert opinion, and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have gemtuzumab ozogamicin by financial year.

Table 2 Estimated number of people in England having gemtuzumab ozogamicin using NICE assumptions

	2018/19	2019/20	2020/21	2021/22	2022/23
Population having gemtuzumab ozogamicin	40	800	850	850	850
Population having induction treatment only with gemtuzumab ozogamicin	10	170	180	180	180

2.3 This report is supported by a local resource impact template. This is because the company has a commercial arrangement (simple discount patient access scheme). This makes gemtuzumab ozogamicin available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount. For enquiries about the commercial arrangement PfizerNICEaccount@pfizer.com.

Savings and benefits

- 2.4 Treatment with gemtuzumab ozogamicin is associated with a reduction in the rate of relapse from remission over time, which reduces the number of relapses and number of people who need haematopoietic stem-cell transplantations. Table 3 shows the details of the estimated reduction in transplants because of people being treated with gemtuzumab ozogamicin.

Table 3 Estimated reduction in transplants for relapse patients in England using NICE assumptions

	2018/19	2019/20	2020/21	2021/22	2022/23
Gemtuzumab ozogamicin and intensive chemotherapy	3	62	116	127	149
Intensive chemotherapy only	5	100	197	226	235
Reduction in transplants	2	38	81	99	86

3 Implications for commissioners

- 3.1 This technology is commissioned by NHS England. Providers are NHS hospital trusts.
- 3.2 Gemtuzumab ozogamicin falls within the programme budgeting category 02I: Cancer, Haematological.

4 How we estimated the resource impact

The population

- 4.1 The annual incidence of people 15 years and over with acute myeloid leukaemia (AML) is around 2,600 ([Acute myeloid leukaemia \(AML\) statistics - Cancer Research UK](#)). Around 950 are cases eligible for treatment with gemtuzumab ozogamicin (company submission). Table 4 shows the details of the population with AML who are estimated to be eligible for treatment with gemtuzumab ozogamicin.

Table 4 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Total population		55,268,067
Incidence of leukaemia for people 15 years and over ¹	0.014	7,800
Proportion of people diagnosed with acute myeloid leukaemia (AML) ²	33.3	2,600
Proportion with untreated de novo disease ³	73.6	1,900
Proportion eligible for intensive chemotherapy ³	63.0	1,200
Less: proportion with unfavourable cytogenic risk profile ³	21.0	-250
Total number of people eligible for treatment with gemtuzumab ozogamicin		950
Total number of people estimated to have gemtuzumab ozogamicin each year from year 2020/21	90.0	850
¹ Leukaemia statistics-Cancer registration statistics		
² Acute myeloid leukaemia (AML) statistics-Cancer Research UK		
³ Company submission		

Assumptions

4.2 The resource impact template assumes that:

- Based on the company submission, 74% of people 15 years and over with AML have untreated de novo disease.
- Based on the company submission, 63% of people with untreated de novo disease are eligible for intensive chemotherapy.
- Based on the company submission, 21% of people eligible for intensive chemotherapy have an unfavourable cytogenic risk profile. It is assumed that 80% of these people would start treatment at presentation and therefore, at peak uptake of 90%, 72% would receive induction therapy while cytogenic test results are not available.

- It is assumed that 90% of the 950 people whose test results show them to have a favourable, intermediate or unknown cytogenetic risk profile will then have consolidation treatment.
- In 2018/19 it is estimated that 5% of people who are eligible for treatment will have gemtuzumab ozogamicin assuming that the treatment will be available for around 1.5 months of the year. Based on the company budget impact submission, the market share is assumed to reach 90% from 2020/21 onwards once a steady state is reached because of the fact that there are currently no other treatments available in England. Uptake is assumed to be half of the peak estimate of 90% for the first 3 months of use.
- In the first year approximately 40 people who have treatment will achieve remission. Based on clinical expert opinion, the number of remissions each year is assumed to reach approximately 680 from 2019/20 onwards, once a steady state is reached.
- The proportion of people relapsing each year is based on the company submission.
- The proportion of people receiving haematopoietic stem-cell transplantation (HSCT) each year is based on the company submission.
- The company estimates the cost of salvage therapy after gemtuzumab ozogamicin therapy to be £27,679.
- The company estimates the cost of salvage therapy cost after chemotherapy only to be £26,939.
- The company estimates the non-curative treatment cost to be £90,426. Costs include inpatient attendances, drug and blood products.
- The company estimates the HSCT year 1 cost be £110,401 with year 2 cost being £14,548.
- The company estimates the graft versus host disease (GVHD) cost to be £26,889.

- The company estimates the incidence of GVHD acute or chronic to be 20.5%.

About this resource impact report

This resource impact report accompanies the NICE guidance on [gemtuzumab ozogamicin for untreated acute myeloid leukaemia](#) and should be read with it.

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