NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

# Resource impact report:
## Gilteritinib for treating relapsed or refractory acute myeloid leukaemia (TA642)

Published: August 2020

## Summary

NICE has recommended gilteritinib monotherapy as an option for treating relapsed or refractory FLT3 mutation-positive acute myeloid leukaemia (AML) in adults only if the company provides gilteritinib according to the commercial arrangement (see section 1).

We estimate that:

- 440 people with relapsed or refractory FLT3 mutation-positive AML are eligible for treatment with gilteritinib
- 340 people will receive gilteritinib from year 2021/22 onwards once uptake has reached 77% as shown in table 1.

**Table 1 Estimated number of people in England receiving gilteritinib**

| | 2020/21 | 2021/22 | 2022/23 | 2023/24 | 2024/25 |
|---|---|---|---|---|---|
| Population receiving gilteritinib each year | 170 | 340 | 340 | 340 | 340 |
| Note: The total number of patients treated each year may alter if the treatment duration were to exceed 1 year. | | | | | |

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

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

# 1 Gilteritinib

1.1 NICE has recommended gilteritinib monotherapy as an option for treating relapsed or refractory FLT3 mutation-positive acute myeloid leukaemia (AML) in adults only if the company provides gilteritinib according to the commercial arrangement. Gilteritinib should not be given as maintenance therapy after a haematopoietic stem cell transplant.

1.2 Current treatment for relapsed or refractory AML is limited. The condition is managed with salvage chemotherapy (a type of chemotherapy offered when a first course of chemotherapy has not worked, or the disease has come back after treatment).

1.3 Gilteritinib is an alternative treatment taken as an oral tablet at home, which is an important quality of life benefit for patients.

1.4 Gilteritinib meets NICE's criteria for a life-extending treatment at the end of life.

# 2 Resource impact of the guidance

2.1 We estimate that:

- 440 people with relapsed or refractory FLT3 mutation-positive AML are eligible for treatment with gilteritinib
- 340 people will receive gilteritinib from year 2021/22 onwards once uptake has reached 77% as shown in table 1.

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

**Table 2 Estimated number of people receiving gilteritinib using NICE assumptions**

| | 2020/21 | 2021/22 | 2022/23 | 2023/24 | 2024/25 |
|---|---|---|---|---|---|
| Population receiving gilteritinib each year | 170 | 340 | 340 | 340 | 340 |
| Note: The total number of patients treated each year may alter if the treatment duration were to exceed 1 year. | | | | | |

2.3 This report is supported by a local resource impact template. Gilteritinib has an agreed patient access scheme which makes it available with a commercial in-confidence discount to the list price. The discounted price of gilteritinib can be put into the template and other variables may be amended. It is the company's responsibility to let relevant NHS organisations know details of the discount. For enquiries about the patient access scheme contact commercial@astellas.com.

## *Benefits and savings*

2.4 Gilteritinib is an oral tablet that is self-managed and can be taken at home therefore improving quality of life compared with having chemotherapy in hospital.

2.5 As an oral therapy gilteritinib could reduce administration costs relative to current salvage chemotherapy options. There may be a reduction in inpatient stays for some people who receive FLAG-IDA and HiDAC. These potential savings can be modelled in the resource impact template.

2.6 Gilteritinib could help to release capacity in hospitals as some people switch from hospital based intravenous infusions to home based oral treatments.

2.7 Clinical evidence shows that people having gilteritinib live longer compared with people having salvage chemotherapy. However, there is considerable uncertainty about long-term survival,

particularly after stem cell transplant. There is no robust evidence of further benefit if someone restarts gilteritinib after stem cell transplant when they have had it before the transplant.

# 3 Implications for commissioners

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

3.2 Gilteritinib falls within the programme budgeting category 02I: Cancer, Haematological.

# 4 How we estimated the resource impact

## *The population*

4.1 In 2017, around 2,460 new cases of adults with acute myeloid leukaemia were recorded in England (Office for National Statistics).

4.2 Table 3 shows the number of people with relapsed or refractory FLT3 mutation-positive acute myeloid leukaemia eligible for treatment with gilteritinib.

**Table 3 Number of people eligible for treatment in England**

| Population | Proportion of previous row (%) | Number of people |
|---|---|---|
| Total population | | 55,977,178 |
| Adult population | | 44,022,560 |
| Incidence of leukaemia in adults[1] | 0.184 | 8,100 |
| Proportion of adults diagnosed with acute myeloid leukaemia (AML)[1] | 30.4 | 2,460 |
| Proportion FLT3-mutation positive[2] | 30 | 740 |
| Proportion with relapsed or refractory disease and eligible for treatment with gilteritinib[2] | 60 | 440 |
| Total number of people estimated to receive gilteritinib each year from year 2021/22[2] | 77 | 340 |

[1] Cancer registration statistics, England.

[2] NHS England submission.

Note: The total number of patients treated each year may alter if the treatment duration were to exceed 1 year.

## *Assumptions*

4.3 The resource impact template assumes that:

- Best supportive care as well as salvage chemotherapy are the relevant comparators. The model also includes azacitidine and mitoxantrone, etoposide and cytarabine (MEC) as comparator regimens. However, expert clinical opinion is that these are not currently used in the NHS. Therefore, uptake has been left at zero but can be amended at a local level.
- Salvage chemotherapy treatments are high-dose cytarabine (HiDAC (AraC), Fludarabine, cytarabine, G-CSF, idarubicin (FLAG-IDA) and hydroxycarbamide.
- Treatment costs for HiDAC (AraC), FLAG-IDA and MEC include chemotherapy delivery costs of £284 on day 1 of every treatment cycle (Healthcare resource group SB13Z: Deliver more complex parenteral chemotherapy at first Attendance) and £284 for each subsequent administration in the cycle

(Healthcare resource group SB15Z Deliver Subsequent Elements of a Chemotherapy Cycle). Taken from NHS national tariff 2019/20.

- Treatment with FLAG-IDA or HiDAC (AraC) can be received as an inpatient or as a day case appointment. The resource impact template assumes all treatments are day case appointments but there is an option to model costs for both treatment settings.
- The inpatient administration cost of £6,613 per cycle is based on a weighted average of the ordinary elective spell tariff prices for admitted patients with Acute Myeloid Leukaemia (HRG codes SA25G – SA25M). Activity data is based on the 2018/19 NHS reference costs.
- Treatment costs for hydroxycarbamide includes oral administration costs of £114 per 30 days (Healthcare resource group SB11Z: Deliver Exclusive Oral Chemotherapy) (NHS national tariff 2019/20).
- Treatment costs for azacitidine includes chemotherapy delivery costs of £142 on day 1 of every treatment cycle (Healthcare resource group SB12Z: Deliver simple parenteral chemotherapy at first Attendance) and £284 for each subsequent administration in the cycle (Healthcare resource group SB15Z Deliver Subsequent Elements of a Chemotherapy Cycle). Taken from NHS national tariff 2019/20).
- The treatment duration with gilteritinib is commercial in confidence. Therefore it should be considered and entered into the model locally. The American Society of Clinical Oncology journal publication cited below reports the median gilteritinib exposure, based on the September 2019 data cut from ADMIRAL, as 4.1 months even though this population includes patients who also received gilteritinib post-HSCT (https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.7514). The gilteritinib SPC notes: Response may be delayed; therefore, continuation of treatment at the prescribed dose for up

to 6 months should be considered to allow time for a clinical response.

- Gilteritinib treatment costs include oral administration costs of £114 per cycle of 28 days (NHS national tariff 2019/20): (Healthcare resource group SB11Z: Deliver exclusively oral chemotherapy).
- The unit cost of best supportive care should be assessed at a local level.

### *Other factors*

4.4 Dose adjustments and the impact on costs have not been modelled and should be considered at a local level.

4.5 The use of gilteritinib could help to reduce the carbon footprint arising from hospital-based intravenous infusions as a result of people switching treatment to home based oral tablets.

## About this resource impact report

This resource impact report accompanies the NICE guidance on gilteritinib for treating relapsed or refractory FLT3 mutation-positive acute myeloid and should be read with it.

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