NHS England: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. Name of the policy proposal: Sorafenib maintenance for adults with FLT3-internal tandem duplication (FLT3-ITD) acute myeloid leukaemia (AML) undergoing allogeneic haemopoietic stem cell transplantation (HSCT) [2259]

2. Brief summary of the proposal in a few sentences

FLT3-ITD AML is an aggressive haematological malignancy, and these individuals are rarely cured with chemotherapy alone. Further treatment may be required with allogeneic haematopoietic stem cell transplantation (allo-HSCT). These individuals have a very poor prognosis with predicted 1-year overall survival rates of below 20%. Sorafenib is a multikinase inhibitor which has been proposed as a potential maintenance therapy in patients with FLT3-ITD AML who have undergone allo-HSCT. Sorafenib following allo-HSCT may target residual disease through selective inhibition of FLT3-ITD positive AML blasts which may reduce relapse and improve overall survival.

The policy recommends that sorafenib is available to adults and post-pubescent children with FLT3-ITD who meet the inclusion criteria.

3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact

Age: older people; middle years; early years; children and young people.	FLT3-ITD AML is often diagnosed in older people. The risk of developing FLT3-ITD AML increases with age and is most common in people over the age of 75 years, although it can occur at any age. The safety of sorafenib has not been established in children. The prevalence of FLT3 mutations in the paediatric population is 13%; the average number of new cases per year in the age range of 0 -19 years is 104. The policy recommends that sorafenib is available to adults with FLT3-ITD who meet the inclusion criteria.	The inclusion criteria in the policy clearly defines the eligible population to maximise equitable access to treatment. Post-pubescent children will be able to access treatment through the medicines for children's policy. Younger children will receive best supportive care. Post-pubescent children are eligible under the Commissioning Medicines for Children in Specialised Services policy, it is proposed that a specialist MDT, which must include paediatricians, determine suitability for sorafenib. The individual health, physical, mental, emotional, educational and developmental needs of the child should be taken into consideration if sorafenib was proposed as a treatment option.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	A cancer diagnosis is defined as a disability under the Equality Act 2010. Receiving sorafenib following a stem cell transplant can result in a significantly lower incidence of disease relapse.	The inclusion criteria in the policy, based on the results from the evidence review, clearly define the eligible patient population to maximise access to treatment. Availability of sorafenib maintenance will provide a treatment option for this group of patients when they meet the inclusion criteria.
Gender Reassignment and/or people who identify as Transgender	No impact was identified on this protected group.	Not applicable
Marriage & Civil Partnership: people married or in a civil partnership.	No impact was identified on this protected group.	Not applicable

Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	FLT3-ITD AML can affect individuals of childbearing age and therefore has the potential for significant impact on pregnancy and maternity (Fracchiolla et al, 2017). <u>Pregnancy</u> There are no safety data on the use of sorafenib in pregnant women. Studies in animals have shown reproductive toxicity including malformations (see section 5.3). In rats, sorafenib and its metabolites were demonstrated to cross the placenta and sorafenib is anticipated to cause harmful effects to the foetus. The Summary of Product Characteristics (SmPC) provides clear advice to individuals who are pregnant and considering treatment with sorafenib. Sorafenib should not be used during pregnancy unless clearly necessary, after careful consideration of the needs of the mother and the risk to the foetus. Women of childbearing potential must use effective contraception during treatment. <u>Lactation</u> It is not known whether sorafenib is excreted in human milk. In animals, sorafenib and/or its metabolites were excreted in milk. Because sorafenib	The SmPC advises against the use of sorafenib in pregnancy unless the benefits clearly outweigh the risks. Any decision for sorafenib to be used in pregnancy will be made by the MDT. Any pregnant woman not treated with sorafenib will continue to receive best standard care in line with current clinical practice. Breast-feeding should be discontinued during treatment with sorafenib. The SmPC advises individuals of childbearing potential must use effective contraception during treatment.

	could harm infant growth and development (see section 5.3), women must not breast-feed during sorafenib treatment. <u>Fertility</u> Results from animal studies indicate that sorafenib can impair male and female fertility (see section 5.3). <u>Impact</u> Sorafenib may have an adverse impact on pregnant women in whom treatment may cause toxicity to the foetus both from a physical and mental health perspective. However, the Policy Working Group consensus is that pregnancy is highly unlikely when undergoing, or post-, transplant, and therefore this would not present an issue. It may also have an adverse impact on the mental and psychological health of individuals who wish to conceive.	
Race and ethnicity[1]	AML is proportionally more prevalent in the white ethnic group (89% of cases)	Data shows that the white ethnic group are disproportionately affected with AML. The

[1] Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to

	than Asian (3.4%) or black (1.9%) ethnic group (Delon et al, 2022). Whilst sorafenib maintenance has the potential to improve outcomes in these patients, it is important to note that individuals from ethnic minority groups have a lower likelihood of receiving an allo-HSCT due to lack of suitable donors. Patients who are white Caucasian have a 72% chance of finding the best match from an unrelated donor, whilst for patients from minority ethnic backgrounds this drops to 37%. Therefore, patients from ethnic minority groups who have the FLT3-ITD mutation may not have as much opportunity to access this treatment because they would not meet the eligibility criterion of an allo-HSCT, and this treatment may widen the gap in outcomes between white Caucasian and ethnic minority groups.	availability of sorafenib maintenance will provide a treatment option for this cohort, who are disproportionately impacted by FLT3-ITD AML. For patients of ethnic minority background, more work needs to take place to understand and address health inequalities around stem cell transplantation using a match from an unrelated donor. This falls outside of the scope of this policy development process and falls under the wider remit of the BMT clinical reference group.
Religion and belief: people with different religions/faiths or beliefs, or none.	Since allo-HSCT is conventionally associated with intensive transfusion support, Jehovah's Witnesses may be limited from receiving allo-HSCT, which means they may not be eligible to	The impact of this policy on Jehovah's Witnesses is acknowledged; there are currently no recommendations to address this identified adverse impact. Individuals who are not treated with

recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

	receive, and benefit from, sorafenib maintenance, and so may be adversely impacted by this policy.	sorafenib will continue to receive best standard care in line with current clinical practice.
Sex: men; women	FLT3-ITD AML disproportionately affects males more than females. In 2016-2018 1,300 new cases of AML were recorded in Females and 1,700 new cases in Males (Cancer Research UK data).	The availability of sorafenib maintenance will provide a treatment option for all those who are eligible, including males, who are disproportionately impacted by FLT3-ITD AML.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	No impact was identified on this protected group.	Not applicable

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your proposal will not impact on patients who experience health inequalities.**

Groups who face health inequalities[2]	**Summary explanation of the main potential positive or adverse impact of your proposal**	**Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact**
Looked after children and young people	This policy may have a potential adverse impact on looked after children and young people, because: 1. Looked-after children and young people may face additional barriers to accessing allogeneic transplantation because the	The adverse impact of this policy on looked after children and young people is acknowledged; there are currently no recommendations to address this identified impact. Individuals who are not treated with sorafenib will continue to receive best standard care in line with current clinical practice.

[2] Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	chances of finding a donor match may be lower in the absence of biological relatives. Therefore, they may have less chance of meeting the policy eligibility criteria to receive sorafenib maintenance. 2. If eligible for treatment under the Commissioning Medicines for Children policy, looked after young people will require someone to bring them to appointments, provide consent for treatment, and guide administering of sorafenib, which may be more difficult than for children with a permanent guardian or carer. Additionally, pre-pubescent children would not be eligible to receive sorafenib maintenance as per policy eligibility criteria.	
Carers of patients: unpaid, family members.	Carers may be indirectly affected by this policy. If the use of sorafenib is successful, it has the potential to prevent relapse, thus improving the health status of the individual. Individuals in whom the	The policy recommends that the suitability of sorafenib as an intervention is assessed by the MDT team. This includes considering of the support, care and follow-up mechanisms a patient would require undergoing the intervention in order to reduce any impact on this group. In addition, the

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	disease relapses will have increased morbidity and mortality. As per section on the protected characteristic on age, FLT3-ITD is mostly diagnosed in older people, and this age group may be more likely to require carers. This policy may benefit carers who support patients with FLT3-ITD AML by reducing the assistance required to complete work, family, and personal tasks. Sorafenib maintenance may therefore increase an individual's active participation, which may reduce their care needs allowing them to participate more in activities of daily living. The use of sorafenib may require ongoing carer support to administer the drug and attend follow-up appointments. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address the consequences of relapsed AML.	MDT will consider the individual patient and carers needs.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	People experiencing homelessness are more likely to have physical health problems, and access to healthcare is difficult for this group (Crisis, 2011). Ethnic minorities (excluding white minorities) make up 32% of all homeless households; as well as the barriers patients from ethnic minorities face in relation to a reduced pool of suitable stem cell donors, homeless people may have even less chance of finding a suitable donor if they are not in contact with biological relatives.	The adverse impact and limitations of this policy on this group and certain sub-groups of this cohort are acknowledged. Commissioned providers and their specialised Haematology Teams should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for homeless patients and facilitate access to the drug, as well as clinical monitoring and follow-up appointments.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	This policy will promote access to sorafenib regardless of criminal status. No specific impact is expected on this group as a result of the implementation of the policy.	Not applicable.
People with addictions and/or substance misuse issues	AML risk increases in individuals who smoke (Cancer Research UK, 2018). Therefore, implementation of this policy will provide a treatment option which would positively impact on this patient group. Additionally, regular contact with healthcare professionals through treatment may provide a good opportunity to promote smoking	Implementation of this policy will provide a treatment option which would positively impact on this patient group.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	cessation and provide ongoing support with this.	
People or families on a low income	Cancer treatment is known to have a financial impact on patients with cancer with 4 in 5 people are affected by financial difficulties and incurring, on average, costs of £570 per month (Macmillan Cancer Care, 2017). However, as sorafenib is an oral tablet it is anticipated that this would reduce the number of hospital visits required and taking time off work compared to treatment with parenteral medications, or any further interventions required if the individual experiences relapse. This could positively impact patients or families on a low income due to a reduction in costs associated with hospital visits and less time off work.	Commissioned providers should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to ensure adequate referral, access and attendance support for people or families on a low income.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	This group may find it hard to understand their condition and the benefits and risks associated with different treatment options.	The policy is specifically for people with a confirmed cancer diagnosis and already accessing healthcare. It is the responsibility of the MDT to ensure that patients are aware of all treatment options available to them and to obtain informed consent for treatment. If additional resources are required for this purpose - e.g., use of an interpreter, EasyRead and translated documents then this should be made available to patients.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
People living in deprived areas	AML incidence rates in England in females are similar in the most deprived quintile compared with the least, and in males are 11% higher in the most deprived quintile compared with the least (2013-2017), (Cancer Research UK, 2018). AML deaths in England are not associated with deprivation (Cancer Research UK, 2018). Deprivation is not known to be a risk factor for AML, however, may be a factor for delayed diagnosis.	Implementation of this policy will provide a treatment option which would positively impact on this patient group. Patients' adverse socio-economic circumstances and impact on treatment delivery, monitoring and follow-up should be considered by the MDT. This will help to ensure, where practicable, treatment is provided as close to the home location of the patient as possible, with priority given to those in deprived areas who may find it challenging to arrange travel, or that travel arrangements are provided by ICBs.
People living in remote, rural and island locations	This policy attempts to ensure there is equal access to treatment regardless of location. The number of hospital visits are expected to be reduced because: 1. Sorafenib is an oral treatment option which will not require frequent clinic attendance 2. Reduced risk of relapse would reduce the necessity for hospital re-admission and clinic visits	Patient convenience is a key consideration and particularly important for patients with ongoing disease. This policy will potentially have a positive impact on this patient group, as sorafenib would provide an oral treatment option. This would make it easier for patients living in remote, rural and island locations who may find it more difficult to access services.
Refugees, asylum seekers or those experiencing modern slavery	Refugees and asylum seekers with an active application or appeal are fully entitled to free NHS care (British Medical	The adverse impact and limitations of this policy on this group and certain sub-groups of this cohort are acknowledged.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	Association, 2020). Refused asylum seekers are not necessarily entitled to free of charge secondary NHS care. Their ability to access care depends on whether the care is immediately necessary/urgent or non-urgent and whether specific exemptions apply. Refused asylum seekers must always receive immediately necessary and urgent treatment regardless of their chargeable status or ability to pay (BMA, 2020). Being a refugee, asylum seeker or experiencing modern slavery are not known to be risk factors for AML. However, it is important to note the link to the impact of this policy on people from ethnic minorities (see earlier section of this document).	Commissioned providers and their specialised Haematology Teams should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for refugees, asylum seekers or those experience modern slavery and facilitate access to the drug, as well as clinical monitoring and follow-up appointments.
Other groups experiencing health inequalities (please describe)	Not applicable.	Not applicable.

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	No X	Do Not Know

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	**Stakeholder testing (planned)**	There was a 2-week stakeholder engagement period with key stakeholders as per NHS England's standard methods.	April 26th-11th May 2023
2	**Public consultation**	Not formally required	
3			

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	The independent evidence review that informed this policy included two randomised controlled trials.	Evidence was not available for cost-effectiveness, quality of life, hospitalisation or activities of daily living.
Consultation and involvement findings		
Research		

Evidence Type	Key sources of available evidence	Key gaps in evidence
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A Policy Working Group was assembled which included haematology specialists, a range of medical clinicians, a public health specialist, a pharmacist and a patient and public voice representative.	

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?	X	X	
The proposal may support?			X
Uncertain whether the proposal will support?			

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	X	X
The proposal may support?		
Uncertain if the proposal will support?		

9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1		
2		
3		

10. Summary assessment of this EHIA findings

This assessment should summarise whether the findings are that this policy will or will not make a contribution to advancing equality of opportunity and/or reducing health inequalities, if no impact is identified please summarise why below. This policy aims to make sorafenib available for adults with FLT3-ITD AML undergoing allo-HSCT and who meet the eligibility criteria outlined in the policy. It is not thought to adversely impact on any other individuals from protected characteristic groups. The policy could provide a treatment option for patients who are currently experiencing the consequences of FLT3-ITD for which there are currently no alternative treatment options to prevent relapse. This policy is informed by the evidence base and the clinical expertise of the policy working group. A national commissioned policy will reduce variation in clinical practice promoting an equity of care nationally for those in which this intervention is indicated. Specifically identified groups that would particularly benefit are those who are Male and of the white ethnic group, who have been identified as disproportionately affected with AML.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care

Division name:	Specialised Commissioning, NHS England
Directorate name:	Chief finance officer
Date EHIA agreed:	30/3/2023
Date EHIA published if appropriate:	