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: Clinical Commissioning Policy: Treatments for Graft versus Host Disease (GvHD) following Haematopoietic Stem Cell Transplantation**
2. **Brief summary of the proposal in a few sentences**

This is a policy to update the current commissioning policy treatments for Graft versus Host Disease (GvHD) following Haematopoietic Stem Cell Transplantation, to include two medicines which have received positive recommendations from NICE:

- belumosudil for the treatment of chronic GVHD.
- ruxolitinib for the treatment of acute GVHD

This is the first EHIA prepared for this policy.

Graft versus Host Disease (GvHD) is a frequent complication of an allogeneic haematopoietic stem cell transplant. It is caused by the patient's body cells recognising donor cells as foreign tissue and attacking these cells. GvHD can affect different areas of the body, most commonly affecting the skin, digestive system and liver. GVHD is categorised as acute or chronic and can occur soon after transplant (2-3 weeks) or many weeks after and can last for months. This policy outlines the commissioned treatment pathways for acute and chronic GvHD. It is an all-ages policy.

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.	The rate of acute and chronic GvHD is similar for adults and children who receive allo-HSCTs. The commissioned therapies cover all ages, however, the new therapy belumosudil that has been approved by NICE is currently licensed for chronic GVHD in patients aged 12 years and over. Ruxolitinib, also approved by NICE, is currently licensed for acute GVHD in patients aged 12 and over.	There is an identified inequity in access to belumosudil and ruxolitinib because they are not licensed for children aged 11 years and under. The NHS England Commissioning Medicines for Children policy has been applied to belumosudil to allow access for post-pubescent children aged below 12 years. The policy may also be applied for ruxolitinib should this be required. The CRG may wish to put forward a preliminary policy for the use of belumosudil and ruxolitinib for pre-pubescent children aged 11 years and under, if there is sufficient evidence to support the application. Should the marketing authorization be extended for belumosudil or ruxolitinib to include children under 12, access can be enabled through application of the NHS England Commissioning Medicines for Children policy.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	There is no documented link between the development of GvHD and disability. Acute and chronic GvHD is a complication that can affect several areas of the body such as, but not limited to, the skin, gastrointestinal tract and liver.	Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)

	Severe GvHD can greatly impact on people's lives and cause disability. Access to extracorporeal photopheresis (ECP) can be onerous and time - consuming, especially for people who suffer with severe GvHD. The addition of belumosudil to the care pathway of chronic GvHD will significantly improve quality of life for individuals with a disability because it is an oral treatment and people can take this at home.	
Gender Reassignment and/or people who identify as Transgender	No impact was identified in this protected group.	Not applicable
Marriage & Civil Partnership: people married or in a civil partnership.	No impact was identified in this protected group.	Not applicable
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	The treatments for acute and chronic GvHD 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. GvHD treatments should not be used during pregnancy unless clearly necessary, after careful consideration of	Pregnant and breastfeeding women will be treated with the best standard of care possible, in line with the risks and benefits of each treatment as decided between the MDT and the patient.

	the needs of the mother and the risk to the foetus. Women of childbearing potential must use effective contraception during treatment.	
Race and ethnicity[1]	Whilst GvHD treatment 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, we may see a lower number of stem cell transplant recipients and therefore with GvHD in ethnic minority groups.	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 is within the remit of the stem cell registries.
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	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 a stem

[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 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.

	means they may not be eligible to receive, and benefit from, GvHD treatments, and so may be adversely impacted by this policy.	cell transplant will continue to receive best standard care in line with current clinical practice.
Sex: men; women	No impact was identified on this protected group.	Not applicable.
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 chances of finding a donor match	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 belumosudil or ruxolitinib 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
	may be lower in the absence of biological relatives. 2. Looked after young people will require someone to bring them to appointments, provide consent for and support for administration of treatment, which may be more difficult than for children with a permanent guardian or carer. Additionally, children aged 11 years and under would not be eligible to receive belumosudil or ruxolitinib.	
Carers of patients: unpaid, family members.	Carers may be indirectly affected by this policy. Appropriate GvHD treatment will potentially improve the health status of the patient. This may benefit carers who support patients with GvHD, by reducing the assistance required to complete work, family, and personal tasks. GvHD treatment may therefore increase an individual's active participation, which may reduce their care needs allowing them to participate more in activities of daily living. Furthermore, appropriate GvHD treatment would lead to a	Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)

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
	reduction in emergency and unscheduled care or prolonged admissions to address the consequences of GvHD. The inclusion of belumosudil in the policy will offer an alternative treatment which could mean that a cohort of patients does not need to travel regularly to receive ECP treatment. This will benefit carers who would ordinarily be required to travel with patients for this purpose.	
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. Whilst regular attendance at clinics for ECP treatment may be a challenge generally for patients, it could potentially	The adverse impact and limitations of this policy on this group and certain sub-groups of this cohort are acknowledged. Commissioned providers 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.

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
	benefit this cohort by offering regular contact with healthcare professionals.	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	This policy will promote access to GvHD treatment 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	GvHD treatments involve regular contact with healthcare professionals which may provide a good opportunity to promote smoking cessation and provide ongoing support with this.	Implementation of this policy will provide a treatment option which would positively impact on this patient group.
People or families on a low income	The oral treatments of GvHD would potentially positively impact patients or families on a low income due to a reduction in costs associated with hospital visits and less time off work. However, some GvHD treatments are accessed by physical attendance at clinic, e.g. ECP. This would have a negative impact on people who are on a low income because of the resource associated with travelling to appointments, as well as necessitating time off work and potential loss of earnings.	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. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)

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 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 diagnosis of GvHD and already accessing healthcare. It is the responsibility of the clinical teams 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.
People living in deprived areas	Deprivation is not known to be a risk factor for GvHD post-transplant. The oral treatments of GvHD would potentially positively impact patients or families on living in deprived areas due to a reduction in costs associated with hospital visits and less time off work. However, some GvHD treatments are accessed by physical attendance at clinic, e.g. ECP. This would have a negative impact on people who live in deprived areas because of the resource associated with travelling to appointments, as well as necessitating time off work and potential loss of earnings.	Patients' adverse socio-economic circumstances and impact on treatment delivery, monitoring and follow-up should be considered by the clinical teams. 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 where possible. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)

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 remote, rural and island locations	This policy attempts to ensure there is equal access to treatment regardless of location. Since some GVHD treatments need to be provided in clinic, this policy may negatively impact people who live in remote, rural and island locations. The inclusion of belumosudil as an option for chronic GvHD would offer an advantage because it would reduce hospital visits because: 1. It is an oral treatment option which will not require frequent clinic attendance. 2. Better management of GvHD would improve quality of life and reduce the necessity for hospital re-admission and clinic visits	Patient convenience is a key consideration and particularly important for patients with ongoing disease. The inclusion of an additional oral line of therapy for chronic GVHD (belumosudil) will have a positive impact on this group of patients. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)
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 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.	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 refugees, asylum seekers or those experience modern

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
	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 GVHD post-transplant. 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).	slavery and facilitate access to the drug, as well as clinical monitoring and follow-up appointments. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)
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	**Policy working group**	Minor update to the policy to include belumosudil and ruxolitinib in the acute and chronic GVHD care pathway	**Q1 24/25**
2			
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		
Consultation and involvement findings		
Research	An independent evidence review took place in 2013.	
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 consultant, 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. Treatments for GvHD will overall advance equality and reduce health inequalities. Whilst it is acknowledged that some of the treatments (such as ECP) require burdensome attendances to hospital that may negatively impact certain patients, the availability of

new treatments (such as belumosudil and ruxolitinib in those age 12 years and over) offer an alternative tablet regimen which will benefit patients as it will reduce the need to attend hospital as frequently.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	CFO
Date EHIA agreed:	
Date EHIA published if appropriate:	