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. Plerixafor for use in patients with transfusion-dependent beta-thalassaemia who are eligible for treatment with exagamglogene autotemcel [2346]

2. Brief summary of the proposal in a few sentences

Beta-thalassaemia is an inherited (genetic) condition that affects the blood and in particular, the beta haemoglobin gene. Some patients with the most severe types of beta-thalassaemia (patients with beta-thalassaemia major and some patients with beta-thalassaemia intermedia) require regular blood transfusions. This is referred to as transfusion-dependent thalassaemia (TDT). TDT is a complex multi-system disease. Iron overload can occur as a result of repeat blood transfusions and can cause tissue damage and impaired function of affected organs, including the heart. Other organs such as the liver and endocrine glands can also be affected, leading to the development of additional, complex health problems.

Exagamglogene autotemcel is a cell therapy which is given to an individual once only as a blood stem cell transplant. For patients with TDT the aim of treatment with exagamglogene autotemcel is to reduce or improve their symptoms. Plerixafor can be used to mobilise stem cells in patients with TDT who are suitable to receive treatment with exagamglogene autotemcel. Plerixafor is given by injection under the skin (subcutaneous injection) and works by mobilising patients' own blood stem cells from the bone marrow into the blood stream. Patients can then undergo a procedure to have their blood stem cells harvested (apheresis). The patient's stem cells can then be treated with exagamglogene autotemcel. The aim of the NHS England commissioning statements is to allow access to plerixafor for patients with TDT who are eligible for treatment with exagamglogene autotemcel, in accordance with NICE TA [ID4015].

The nature of severe beta-thalassaemia means that current patients with capacity to benefit from this treatment are likely to already be known to specialist services.

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.	Beta-thalassaemia is an inherited condition. Exagamglogene autotemcel is licensed for the treatment of transfusion-dependent β-thalassemia in patients 12 years of age and older.	The proposal is for plerixafor to be given to the same patient population as exagamglogene autotemcel.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Iron overload can occur as a result of repeat blood transfusions for people with TDT and can cause tissue damage and impaired function of affected organs, including the heart. Other organs such as the liver and endocrine glands can also be affected, leading to the development of additional, complex health problems.	Plerixafor will be used to mobilise stem cells in patients who are suitable to receive exagamglogene autotemcel. This is to ensure that a sufficient quantity of the patient's own blood stem cells can be harvested and treated with exagamglogene autotemcel.
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and being transgender are not known to be risk factors for TDT. This proposal will promote access to plerixafor regardless of gender reassignment or being transgender.	N/A

Marriage & Civil Partnership: people married or in a civil partnership.	Marriage status is not known to be a risk factor for TDT. This proposal will promote access to plerixafor regardless of marriage status.	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	There are no adequate data on the use of plerixafor pregnancy. It should not be used in pregnant patients.	Plerixafor should not be used in pregnancy. Women of childbearing potential must use effective contraception during treatment with plerixafor.
Race and ethnicity[1]	Thalassemia is mainly seen in those with an Asian and Southern Mediterranean heritage. This proposal is expected to have a positive impact on this characteristic as part of a new treatment option.	Plerixafor will be used to mobilise stem cells in patients who are eligible to receive exagamglogene autotemcel.
Religion and belief: people with different religions/faiths or beliefs, or none.	Religion is not known to be a risk factor for TDT. This proposal will promote access to plerixafor regardless of religion.	N/A
Sex: men; women	Sex is not known to be a risk factor for TDT. This proposal will promote access to plerixafor regardless of sex.	N/A
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not known to be a risk factor for TDT. This proposal will promote access to plerixafor regardless of sexual orientation.	N/A

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	There is no identified impact of this proposal on this group who face health inequalities although it is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group.
Carers of patients: unpaid, family members.	This proposal should have a positive impact for carers as the overall treatment will reduce the frequency and severity of symptoms and access to emergency care. It is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	There is no identified impact of this proposal on this group who face health inequalities although it is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	There is no identified impact of this proposal on this group who face health inequalities although it is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
People with addictions and/or substance misuse issues	There is no identified impact of this proposal on this group who face health inequalities although it is recognised that	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and

	accessing services may be more challenging in this group.	barriers to accessing treatment services for patients from this group
People or families on a low income	The overall treatment will likely reduce the financial burden on families from frequent trips to hospital.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	There is no identified impact of this policy proposition on this group who face health inequalities although it is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
People living in deprived areas	There is no identified impact of this policy proposition on this group who face health inequalities although it is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
People living in remote, rural and island locations	This proposal should have a positive impact on people living in remote, rural and island locations as the overall treatment will reduce the frequency and severity of symptoms and access to emergency care.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group
Refugees, asylum seekers or those experiencing modern slavery	There is no identified impact of this policy proposition on this group who face health inequalities although it is recognised that accessing services may be more challenging in this group.	This treatment is likely to reduce the burden of frequent trips to hospital for patients and carers. Services should include individual level assessment of how they can mitigate the challenges and barriers to accessing treatment services for patients from this group

Other groups experiencing health inequalities (please describe)	There are no further direct negative or positive impacts of this proposal on any other groups experiencing health inequalities.	N/A

References:

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			
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	Yannaki, E. *et al.* (2013) 'Hematopoietic stem cell mobilization for gene therapy: Superior	

	mobilization by the combination of granulocyte–colony stimulating factor plus plerixafor in patients with β-thalassemia major', *Human Gene Therapy*, 24(10), pp. 852–860. doi:10.1089/hum.2013.163.	
Consultation and involvement findings	None	
Research	No pending research is known	
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 paediatric and adult haematology specialists, a public health specialist, pharmacists and a patient and public voice representative. This group was supported by the Haemoglobinopathies Clinical Reference Group and the Blood and Infection Programme of Care.	

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?			
The proposal may support?	X	X	
Uncertain whether the proposal will support?			X

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 proposal aims to make plerixafor available for mobilisation of stem cells in patients with transfusion-dependent thalassaemia who are eligible to receive treatment with exagamglogene autotemcel. Stem cell mobilisation will ensure that a sufficient quantity of a patient's own blood stem cells can be harvested and treated with exagamglogene autotemcel.

The overall treatment with exagamglogene autotemcel has the potential to significantly improve the quality of life of patients with TDT by relieving the symptoms of disease and preventing acute hospital admissions. No adverse impacts of this proposal have been identified.

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:	