

NHS England and NHS Improvement: 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 proposal (policy, proposition, programme, proposal or initiative)¹:** Plerixafor for stem cell mobilisation in adults and children
2. **Brief summary of the proposal in a few sentences**

Haematopoietic stem cells (HSC) are special cells produced by bone marrow that can turn into different types of blood cells. An HSC transplant replaces damaged blood cells with healthy ones. HSC Transplants can be allogeneic which involves replacing a person's bone marrow stem cells with stem cells from a donor. Autologous transplantation uses the person's own peripheral blood stem cells (PBSCs).

Before an autologous transplant is undertaken, 'mobilisation' is needed to dislodge the haematopoietic stem cells from the bone marrow and increase the number of PBSCs in the circulating blood flow. The circulating PBSC can then be collected using a cell separator in a procedure called apheresis.

In around 10-20% of cases, current mobilisation treatment fails, with additional attempts at mobilisation with higher dose chemotherapy (part of the current treatment pathway) only being successful in up to 20% of these patients.

Plerixafor is currently commissioned for patients with specific blood cancers (multiple myeloma and lymphoma) in people of any age, and specific solid tumours in people aged 24 years or under, but not for patients with other blood cancers or people aged over 24 years with specific solid tumours. NHS England has developed a policy proposition to routinely commission plerixafor in cases of a failed mobilisation attempt (rescue treatment) or in people with low levels of circulating stem cells (pre-emptive treatment) for this group of patients that were not in scope of the original policy.

¹ Proposal: We use the term proposal in the remainder of this template to cover the terms initiative, policy, proposition, proposal or programme.



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
<p>Age: older people; middle years; early years; children and young people.</p>	<p>This policy proposition positively impacts on people aged over 24 years of age with solid tumours, as this group were previously out of scope of the commissioning policy for use of this intervention to support successful autologous HSCT.</p>	<p>This policy propositions scope is extended to include these groups in relation to age.</p>
<p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>People with cancers can be included in the protected characteristic of disability given the long-term nature and level of impairment cancer and the treatments associated with cancer can bring. This policy proposition seeks to include more patients living with types of cancer previously out of scope of the policy, increasing access to this treatment for people with disabilities. The policy proposition also excludes specific types of cancer, namely leukemia, as use of plerixafor in this indication could increase the number of leukemia cells within the blood stream, which would contaminate an apheresed</p>	<p>This policy propositions scope is extended to include these groups. The exclusion for patients with leukemia is on the basis of clinical safety.</p>

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
	cells and risk spreading the cancer to other parts of the body.	
Gender Reassignment and/or people who identify as Transgender	This policy proposition does not positively or negatively impact on people with this characteristic.	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	This policy proposition does not positively or negatively impact on people with this characteristic.	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Plerixafor use in pregnancy is an exclusion in this policy proposition, linked to safety concerns over the impact of its use on the fetus.	The licensing of plerixafor states that there is no adequate data on the use of plerixafor in pregnant women, but based on the pharmacodynamic mechanism of action, plerixafor is suggested to cause congenital malformations when administered during pregnancy.
Race and ethnicity²	This policy proposition does not positively or negatively impact on people with this characteristic.	N/A
Religion and belief: people with different religions/faiths or beliefs, or none.	This policy proposition does not positively or negatively impact on people with this characteristic.	N/A

² 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.

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
Sex: men; women	This policy proposition does not positively or negatively impact on people with this characteristic.	N/A
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	This policy proposition does not positively or negatively impact on people with this characteristic.	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 ³	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 proposition does not positively or negatively impact on this group who experience health inequalities above the age-related aspects outlined above.	N/A
Carers of patients: unpaid, family members.	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A

³ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

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Groups who face health inequalities³	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.	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
People with addictions and/or substance misuse issues	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
People or families on a low income	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
People living in deprived areas	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
People living in remote, rural and island locations	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A

Groups who face health inequalities ³	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
Refugees, asylum seekers or those experiencing modern slavery	This policy proposition does not positively or negatively impact on this group who experience health inequalities.	N/A
Other groups experiencing health inequalities (please describe)	N/A	N/A

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	X	No	Do Not Know
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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	The policy proposition was sent out to registered stakeholders for comment over a two-week period, where issues over equalities and health inequalities within the policy proposition can be raised. The stakeholder list was reviewed to identify any missing key stakeholders. Anthony Nolan Trust, British Oncology Pharmacy Association (BOPA) and UK Oncology Nursing Society (UKONS) were identified and invited to take	October 2019

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		part in stakeholder testing. All respondents actively supported the policy proposition.	
2	PPV and professional body involvement in the Policy Working Group (PWG), with the Clinical Reference Group and Programme of Care Assurance Group oversight.	PPV members have been involved in the development of the policy via representation on the PWG and being represented on the CRG and PoC that oversee workstreams linked to the PoC. This provides an opportunity for any concerns linked to equalities duties or health inequalities are considered prior to the policy progressing to the next stage of development.	September 2019- May 2020
3	Review with the Patient and Public Voice Assurance Group	Discussion with the PPVAG chair to confirm that 13Q is not triggered to require further public and patient involvement in the commissioning policy development.	May 2020

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	<p>Horwitz ME, Long G, Holman P et al. (2012) Efficacy and safety of hematopoietic stem cell remobilization with plerixafor+G-CSF in adult patients with germ cell tumors. Bone marrow transplantation 47(10): 1283-6</p> <p>Lee SY, Sanchorawala V, Seldin DC et al. (2014) Plerixafor-augmented peripheral blood stem cell mobilization in AL amyloidosis with cardiac involvement: a case series. Amyloid (3): 149–53</p> <p>Jaimovich G, Castro M, Ostriz B, Fernandez M, Silveyra D, Campestri R. (2016). Plerixafor, cyclophosphamide and G-CSF and blood cell mobilization in a patient with acute promyelocytic leukaemia. Journal of Clinical Apheresis, 32, pp 592-593.</p>	

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Evidence Type	Key sources of available evidence	Key gaps in evidence
	Worel N, Apperley JF, Basak GW et al. (2012) European data on stem cell mobilization with plerixafor in patients with nonhematologic diseases: an analysis of the European consortium of stem cell mobilization. <i>Transfusion</i> 52(11): 2395-400.	
Consultation and involvement findings	Involvement of the patient and public voice assurance members of the policy working group, CRG and PoC.	
Research	/	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	<p>British Society of Blood and Marrow Transplantation, 2012. Adult BSBMT Indications Table 2012. http://bsbmt.org/wp-content/uploads/2013/12/Indications-Table-Updated-Feb2012-PDF-Version.pdf accessed on 18/06/19</p> <p>British Society of Blood and Marrow Transplantation, 2011. Paediatric BSBMT Indications Table 2011. http://bsbmt.org/wpcontent/uploads/2013/12/UK_Paed_BMT_Gp_HSCT_Indications_23Dec111.pdf accessed on 18/06/19</p> <p>European Medicines Agency. 2019. Mozobil, Summary of Product Characteristics. accessed on 18/06/19</p> <p>European Medicines Agency. 2018. Mozobil European public assessment report.</p> <p>NHS. 2018. Stem cell and bone marrow transplants. https://www.nhs.uk/conditions/stem-cell-transplant/ accessed 21/05/19</p> <p>NHS England. 2019, Evidence review for policy 1902.</p>	

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Evidence Type	Key sources of available evidence	Key gaps in evidence
	Douglas KW, Gilleece M, Hayden P et al. (2017) UK consensus statement on the use of plerixafor to facilitate autologous peripheral blood stem cell collection to support high-dose chemoradiotherapy for patients with malignancy. Journal of Clinical Apheresis 33(1):46-59	

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	
The proposal may support?	X		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?		
The proposal may support?	X	X
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	N/A	
2		
3		

10. Summary assessment of this EHIA findings

This assessment should summarise whether the findings are that this proposal 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 proposal will contribute to advancing equality of opportunity for people based on age and disability, noting the clinical safety grounds inequalities for people who are pregnant and who have leukemia continue to be out of scope from this policy.

11. Contact details re this EHIA

Team/Unit name:	Blood & Infection National Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Finance
Date EHIA agreed:	03 June 2020