NHS

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 proposal (policy, proposition, programme, proposal or initiative):** Allogeneic Haematopoietic Stem Cell Transplant for patients with X-linked cerebral adrenoleukodystrophy (Adults) [2203]

2. **Brief summary of the proposal in a few sentences**

Allogeneic Haematopoietic Stem Cell (allo-HSCT) is recommended to be available as a routinely commissioned treatment option for adult patients with X-linked cerebral adrenoleukodystrophy (C-ALD).

For the purposes of this EHIA, the term ‘male’ refers to patients of male sex (with an “XY” chromosome pattern) unless otherwise stated.

The clinical features of X-ALD are varied, with different aspects of the disease appearing at different times. There are three core clinical syndromes and patients may go on to develop any combination of these syndromes. Males with X-ALD may first present in childhood with adrenal insufficiency (problems with the adrenal gland functioning), which means they need life-long medications. They may also present with a second syndrome of rapid neurological damage due to an inflammatory leukodystrophy (loss of the white matter within the brain), which can affect learning, behaviour, vision and physical functioning (C-ALD). The third clinical syndrome is a slowly progressive spinal cord disease known as adrenomyeloneuropathy (AMN). AMN normally presents in men in their thirties who may or may not have adrenal insufficiency. AMN leads to stiffness and weakness of the legs, including problems with balance and difficulty controlling bladder and bowel function. Patients end up wheelchair bound and requiring catheterisation (a procedure to empty the bladder). This policy will focus on C-ALD.

Allo-HSCT is intended to prevent further progression of C-ALD and is currently the only treatment available targeting cerebral disease progression. Paediatric patients under the age of 18 years can already benefit from allo-HSCT through the NHS England Clinical Commissioning Policy (B04/S/b), but for males who go on to develop C-ALD as an adult, this treatment option is currently unavailable.

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.	Allo-HSCT is already available for male patients less than 18 years old so this policy provides equitable access to all male patients aged 18 years of age and over in need of this treatment at the same time and level of disease severity.	There are no negative impacts of the introduction of the policy as this provides an intervention which is not currently available for adults. The aim of this policy is to address the current age-related inequity of provision and increase equity of access to this treatment.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	C-ALD causes progressive neuro-cognitive changes which leads to disturbances in speech, movement, cognition and behaviour and ultimately results in death. This policy aims to reduce progressive neuro-cognitive disability and to maintain cognitive functions in all those affected individuals.	This policy suggests that individuals are selected for HSCT based on a Multi-Disciplinary Team (MDT) assessment of suitability which considers an individual's long-term conditions and current cognitive and neurological baseline. This aims to promote the best possible outcomes for individuals with HSCT, and to minimise the risks associated with this procedure.
Gender Reassignment and/or people who identify as Transgender	C-ALD is not known to have a higher prevalence in individuals who identify as transgender or gender reassignment.	This policy is based on sex and not gender identity. It would include all individuals who meet the inclusion criteria for HSCT. If a patient of male sex who identified as female/non-binary developed C-ALD they would be eligible for allo-HSCT if they met the inclusion criteria.
Marriage & Civil Partnership: people married or in a civil partnership.	Marriage or civil partnership is not linked to C-ALD.	This policy would include all individuals who meet the inclusion criteria for HSCT and is not known to adversely impact individuals in marriage or civil partnerships.

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
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Women are not known to develop C-ALD.	This policy is focused on adult males only. If there is a family history of C-ALD, pre-natal genetic counselling for potentially affected families is the responsibility of the maternity services network.
Race and ethnicity[1]	C-ALD has prevalence of 1 in 20,000 and a higher incidence in patients with African or Latino descent.	This policy aims to offer equitable access to all patients affected by C-ALD, noting that particular support would need to be targeted at patients from ethnic minority backgrounds with a higher incidence of C-ALD. This may include the services of an interpreter to help with any language barriers and to ensure that relevant information is accessible to all eligible individuals.
Religion and belief: people with different religions/faiths or beliefs, or none.	C-ALD is not known to have a higher prevalence in religious or belief groups.	This policy would include all individuals who meet the inclusion criteria for allo-HSCT. There may be religious or belief groups who oppose transplantation. All eligible individuals who meet the inclusion criteria will have the risks and benefits of the transplant procedure explained to them so that they can make an informed decision about their treatment. Allo-HSCT remains the only proposed treatment option for patients with C-ALD. There may be the potential for gene

[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.

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
		therapy treatments in the future, but this is outside the scope of this policy.
Sex: men; women	As an X-linked condition the presentation of X-ALD is more severe in males as they only have one "X" chromosome, as males have an "XY" chromosome pattern. Women have an "XX" chromosome pattern, which means if they inherit a faulty copy of the gene they still have the possibility of a working copy. C-ALD is not known to affect female patients. For these reasons, the policy is for adult males.	This policy is for adult males, as women do not develop C-ALD. Therefore, policy is not thought to adversely impact this population group.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	C-ALD is not known to have a higher prevalence dependent on sexual orientation.	This policy would include all individuals who meet the inclusion criteria for HSCT and is not known to adversely impact individuals based on sexual orientation.

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	Allo-HSCT for this indication is currently available for male patients less than 18 years of age, so children and young people would not be impacted by this policy.	This policy is for adults as the intervention is currently available already available for individuals less than 18 years of age.
Carers of patients: unpaid, family members.	An aim of allo-HSCT is to reverse or to halt the progression of the neuro-cognitive changes seen in C-ALD. This could benefit carers and unpaid family members if an individual could retain and/or regain skills and independence. Additionally, this may alleviate the psychological distress currently experienced by carers as patients experience progressive disease with no active treatment options which means they are unable to work or participate fully in family life.	The policy suggests engaged and shared decision making for suitable individuals and their families. The policy aims to stabilise or reverse the progressive neuro-cognitive changes seen in C-ALD. This may positively impact on carers and family members as the care burden may be reduced or removed. The decision for allo-HSCT will be made in combination with specialists, patients and their families and carers.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	Individuals who meet the inclusion criteria would be equally eligible for consideration of allo-HSCT. If individuals are homeless or staying in temporary accommodation it may be challenging for them to engage with the care (including access to GP services) to support an intervention like allo-HSCT.	A national clinical policy aims to promote equity in access to treatment for all individuals who meet the inclusion criteria. Homeless individuals who meet these criteria may be at increased risk of post-operative infection due to poor living conditions. Commissioned providers should work with the patient and other relevant agencies (e.g., GP, local authority, charities) to mitigate the risk for homeless patients.

[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
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	C-ALD is a rare condition and is not known to have an increased prevalence in individuals in the criminal justice system.	All individuals who meet the inclusion criteria would be eligible for the intervention. A local care-coordinator would need to be designated for affected individuals residing in prison to ensure adequate measures are taken to reduce post-operative infection risk. Commissioned provides should work with the patient and other relevant agencies (e.g., GP, local authority, charities) to mitigate the risk for people in the criminal justice system and to help support follow-up care.
People with addictions and/or substance misuse issues	C-ALD is a rare condition and is not known to have an increased prevalence in individuals with substance or misuse issues.	The policy suggests an MDT assessment of suitability which takes into consideration an individual's unique circumstances. Given this assessment it is not known to adversely impact on individuals with substance and misuse issues.
People or families on a low income	The procedure of allo-HSCT is proposed to be provided as part of routine commissioning. This means the procedural cost would be met by the NHS.	The policy would reduce the inequity currently faced by adult male patients, as currently this treatment is not available on the NHS to males aged 18 years old or older. This policy aims to offer the intervention to all individuals who meet the inclusion criteria, this could be seen as a positive impact on people or families on a low income (as currently the intervention is only available if an individual or family pay for this intervention). MDT assessment of these patients should include discussions about the delivery location of allo-HSCT. Where possible, treatment should be provided at the specialist centre as close to the

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
		home location of the patient as possible, with priority given to patients who, due to socioeconomic circumstances, may find it more difficult to access treatment that requires longer distance travel.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	The policy suggests shared decision making between the clinical team, patients, and their family. This could be in discussion and/or other forms of information based on an individuals' need.	Shared decision-making should be used as best practice, this would include clinicians facilitating informed decisions for an individual based on need. This can be through various mediums including verbal as well as written shared decision-making tools, translated and Easy Read materials.
People living in deprived areas	The policy would apply to all individuals meeting the inclusion criteria.	The policy aims to reduce the inequity in service delivery. As part of the proposed holistic MDT discussion, consideration must be given to ensure, where practicable, treatment is provided as close to the home location of the patient as possible, with priority given to those patients living in deprived areas who may find it more difficult to make travel arrangements.
People living in remote, rural and island locations	The policy would apply to all individuals meeting the inclusion criteria.	The policy aims to reduce the inequity in service delivery. As part of the proposed holistic MDT discussion, consideration must be given to ensure, where practicable, treatment is provided as close to the home location of the patient as possible, with priority given to those patients living in remote, rural and island locations who may find it more difficult to make travel arrangements.

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
Refugees, asylum seekers or those experiencing modern slavery	The policy would apply to all individuals meeting the inclusion criteria.	Individuals meeting the inclusion criteria for the policy would be eligible for the intervention. Refugees, asylum seekers or those experiencing modern slavery who meet these criteria may be at increased risk of post-operative infection due to poor living conditions. Commissioned providers should work with the patient and other relevant agencies (e.g., GP, local authority, charities) to mitigate the risk for people who are refuges, seeking asylum or experiencing modern slavery.
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 X	No	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	The Policy and supportive documentation have been shared with PWG, including PPVAG members.	PPVAG and PWG shared their clinical experience to understand and address the key areas of inequity in cerebral adrenoleukodystrophy.	July 2022

2	The Policy and supportive documentation will be shared for consultation.	The Policy was agreed not to require public consultation by the PPVAG.	February 2023
3	The findings of the consultation process will be shared with the PPVAG to assure the decision process.		

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	An independent external evidence review has been conducted by Solutions for Public Health (SPH).	No evidence was returned for the cost-effectiveness of the proposed treatment.
Consultation and involvement findings	Stakeholder testing was undertaken during 12.12.2022 and 09.01.2023	No gaps in evidence were identified
Research	Not applicable	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The PWG includes members from patient advocacy group and clinical experts, the metabolic and BMT clinical reference groups and their registered stakeholders were included in the stakeholder consultation.	

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	X
The proposal may support?			

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	N/A	
2	N/A	
3	N/A	

10. Summary assessment of this EHIA findings

This policy aims to address a current age inequity in care provision, by the recommendation of routine commissioning for allo-HSCT in adult males for C-ALD, an intervention currently available for male paediatric patients. The policy is focused on adult males due to the X-linked nature of the disease. Women are not known to develop C-ALD. Allo-HSCT for C-ALD is currently commissioned as a treatment option for paediatric male patients up until the age of 18 years, and this policy aims to reduce this age-related inequity of access by making this option available to adult males who meet the eligibility criteria. This EHIA acknowledges that there may be

religious or belief groups who oppose allo-HSCT as a treatment option. All eligible patients must be given adequate information of the risks and benefits surrounding the transplantation and allowed the opportunity to make an informed decision about their treatment. As C-ALD has a higher prevalence in patients of African or Latino descent, targeted support including the use of an interpreter should be offered to this group where applicable. Commissioned providers should work with the patient and other relevant agencies (e.g. GP, local authority, charities) to mitigate the procedure-associated risks for vulnerable patient groups and help ensure ongoing follow-up care as appropriate.

11. Contact details re this EHIA

Team/Unit name:	NHS England Specialised Commissioning
Division name:	Specialised Commissioning
Directorate name:	CFO
Date EHIA agreed:	19/10/22
Date EHIA published if appropriate:	