

## 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):** Imlifidase enabled deceased donor kidney transplantation [2304]
2. **Brief summary of the proposal in a few sentences**

Highly sensitised patient refers to a patient with human leukocyte antigen (HLA) antibodies present in their blood, acquired via pregnancy, transfusion of blood products, and/or prior transplantation. HLA antibodies may cause antibody-mediated rejection of the new transplanted graft leading to graft failure. These patients are considered higher risk transplant patients and will wait longer to match with a compatible deceased organ donor than non-sensitised patients as they must wait for donors that don't have HLA antigens which their antibodies will recognise. Highly sensitised patients require dialysis for longer which can have a significant adverse event on both quality and length of life. It also reduces the fitness and strength of the patient for transplantation, which can render them ineligible for transplant.

For highly sensitised patients, imlifidase has the potential to desensitise patients prior to receiving a deceased donor kidney transplant. Imlifidase is an enzyme that temporarily breaks down human immunoglobulin G (IgG) antibodies. Imlifidase is a high-cost drug and has been supported by NICE for use by the NHS under specific provisos. This rapid policy statement aims to ensure appropriate and equitable use of and access to Imlifidase for patients across the UK.

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><b>Age:</b> older people; middle years; early years; children and young people.</p>	<p>HLA sensitization can occur in people of all ages as the risk factors are not age related (except for pregnancy).</p> <p>This commissioning statement is expected to have a positive effect on the overall survival and overall outcomes for adults who are highly sensitised by ensuring appropriate and equitable access to imlifidase. The drug is licensed for patients over the age of 18 however pre-pubescent children can be considered under NHS England's medicine for children's policy.</p>	<p>All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.</p>
<p><b>Disability:</b> physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>Whilst disability is not a risk factor for HLA sensitization, being highly sensitized can lead to disability, as it requires people to rely on dialysis for longer which can weaken patients, leading to mobility issues and poorer quality of life.</p> <p>This commissioning statement is expected to have a positive effect on the overall survival and overall outcomes of patients who are highly sensitised by ensuring appropriate and equitable access to imlifidase.</p>	<p>All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group. For patients who aren't able to consent for the use of this drug, standard consenting process will allow use in those with learning disabilities</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
<b>Gender Reassignment and/or people who identify as Transgender</b>	Gender reassignment and identifying as transgender are not known to be risk factors for HLA sensitization. This policy proposition will promote access to imlifidase enabled deceased donor kidney transplantation regardless of gender status.	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.
<b>Marriage &amp; Civil Partnership:</b> people married or in a civil partnership.	Marriage status is not known to be a risk factor for HLA sensitization. This policy proposition will promote access to imlifidase enabled deceased donor kidney transplantation regardless of marriage status.	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.
<b>Pregnancy and Maternity:</b> women before and after childbirth and who are breastfeeding.	<p>People with kidney failure requiring transplant who have been pregnant will be higher risk for becoming highly sensitised as pregnancy is a risk for HLA antibody acquisition.</p> <p>This policy is expected to have a positive effect on the overall survival and overall outcomes of patients who are highly sensitised by ensuring appropriate and equitable access to imlifidase.</p>	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.

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
<b>Race and ethnicity</b> <sup>1</sup>	<p>People from ethnic minorities, including Afro-Caribbeans and Asians will wait longer for transplants and have lower organ donation rates.</p> <p>Statistics from the ODT clinical show that over the last five years there has been an 8% increase in ethnic minority patients waiting on the list, 1% increase in transplants for ethnic minority patients (all organs), 12% fall in ethnic minority living donors and 4% fall in ethnic minority deceased organ donors.</p> <p>This policy is expected to have a positive effect on the overall survival and overall outcomes of patients who are highly sensitised by ensuring appropriate and equitable access to imlifidase.</p>	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.
<b>Religion and belief:</b> people with different religions/faiths or beliefs, or none.	Religion is not known to be a risk factor for HLA sensitization. This commissioning statement will promote access to imlifidase enabled deceased	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not

<sup>1</sup> 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
	donor kidney transplantation regardless of religion.	considered to have an adverse impact on this protected characteristic group.
<b>Sex:</b> men; women	<p>Data from NHS Blood and Transplant show that more male than female adults are registered on the transplant list. However, more females are sensitised (due to previous pregnancy).</p> <p>This commissioning statement is expected to have a positive effect on the overall survival and overall outcomes of patients who are highly sensitised by ensuring appropriate and equitable access to imlifidase.</p>	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.
<b>Sexual orientation:</b> Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not known to be a risk factor for HLA sensitization. This commissioning statement will promote access to imlifidase enabled deceased donor kidney transplantation regardless of sexual orientation.	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.

#### 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 <sup>2</sup>	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
<b>Looked after children and young people</b>	<p>HLA sensitization can occur in people of all ages as the risk factors are not age related (except for pregnancy).</p> <p>This commissioning statement is restricted to adults in line with the NICE TA and licencing of imlifidase. However, pre-pubescent children can be considered under NHS England's medicine for children's policy.</p>	<p>The commissioning statement recommends that the suitability of imlifidase enabled deceased donor kidney transplantation is assessed by the MDT team.</p> <p>This includes considering the support, care, and follow-up mechanisms a patient would require undergoing the intervention.</p> <p>The ability to attend regular hospital appointments needs to be part of that consideration.</p>
<b>Carers of patients:</b> unpaid, family members.	<p>This commissioning statement has the potential to improve an individual's health status and reduce morbidity. Imlifidase enabled kidney transplantation may reduce the care needs of patients, allowing them to participate more in activities of daily living. Additionally, kidney transplantation will negate the need for dialysis, thereby potentially relieving pressures on carers as they will not need to support patients getting to and from hospital for appointments.</p> <p>This commissioning statement may benefit carers who support patients with kidney failure by reducing the assistance required to complete work, family, and</p>	<p>The commissioning statement recommends that the suitability of imlifidase enabled deceased donor kidney transplantation is assessed by the MDT team.</p> <p>This includes considering the support, care, and follow-up mechanisms a patient would require undergoing the intervention.</p> <p>The ability to attend regular hospital appointments needs to be part of that consideration.</p>

<sup>2</sup> Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities <sup>2</sup>	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
	personal tasks and reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced disease.	
<b>Homeless people.</b> People on the street; staying temporarily with friends /family; in hostels or B&Bs.	<p>This group may be less likely to enter the patient pathway due to access issues e.g., not registered with a General Practitioner. They may also find it more difficult to maintain engagement with a course of treatment.</p> <p>Imlifidase enabled kidney transplantation would require extensive workup to determine eligibility which patients would need to engage with. This potentially could be a barrier for access to some patients.</p>	<p>NHS England is producing the imlifidase enabled deceased donor kidney transplantation policy to increase equitable access for anyone who may benefit from the intervention.</p> <p>Commissioned transplant providers 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 treatment, as well as clinical workup, ongoing monitoring and follow-up appointments.</p>
<b>People involved in the criminal justice system:</b> offenders in prison/on probation, ex-offenders.	<p>Being in the criminal justice system is not known to be a risk factor for being highly sensitised.</p> <p>This commissioning statement will promote access to imlifidase regardless of criminal status.</p>	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not considered to have an adverse impact on this protected characteristic group.
<b>People with addictions and/or substance misuse issues</b>	Addiction and substance misuse is not known to be a risk factor for being highly sensitised.	All patients who meet the inclusion criteria would be considered for imlifidase enabled deceased donor kidney transplantation. The proposal is therefore not

<b>Groups who face health inequalities<sup>2</sup></b>	<b>Summary explanation of the main potential positive or adverse impact of your proposal</b>	<b>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</b>
	<p>People with addiction/and or substance misuse issues might find it harder to maintain engagement with the course of treatment.</p> <p>This commissioning statement will promote access to imlifidase regardless of addiction issues.</p>	<p>considered to have an adverse impact on this protected characteristic group.</p>
<b>People or families on a low income</b>	<p>Imlifidase enabled kidney transplantation will need to be done in specialist centres, which may be far for some patients to travel to. This may be a barrier for them accessing treatment.</p> <p>However, this would be offset by reducing the need to travel to hospital regularly for dialysis sessions.</p>	<p>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.</p>
<b>People with poor literacy or health Literacy:</b> (e.g. poor understanding of health services poor language skills).	<p>This group may find it hard to understand their condition and the benefits and risks associated with different treatment options. This might impact on their ability to access treatment or maintain involvement in a treatment regime.</p>	<p>Shared decision making should be used using appropriate mediums including verbal, written shared decision-making tools, translated, and Easy Read materials.</p> <p>The provision of treatment should be provided in a way to assist those with poor health or literacy skills. A holistic assessment of an individual should be undertaken by the prescribing physician to assess their suitability and understanding of compliance barriers for imlifidase enabled deceased donor kidney transplantation.</p>



<b>Groups who face health inequalities<sup>2</sup></b>	<b>Summary explanation of the main potential positive or adverse impact of your proposal</b>	<b>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</b>
<b>People living in deprived areas</b>	<p>Imlifidase enabled kidney transplantation will need to be done in specialist centres, which may be far for some patients to travel to. This may be a barrier for them accessing treatment.</p> <p>However, this would be offset by reducing the need to travel to hospital regularly for dialysis sessions.</p>	<p>This policy statement will increase geographic access of providers of imlifidase enabled deceased donor kidney transplantation which is not currently available.</p> <p>Patients' socio-economic circumstance will be considered by an appropriately constituted MDT. This will help to ensure treatment is provided as close to the home location of the patient as possible. Access to travel arrangements provided by Integrated Care Boards (ICBs) needs to be part of this.</p>
<b>People living in remote, rural and island locations</b>	<p>Imlifidase enabled kidney transplantation will need to be done in specialist centres, which may be far for some patients to travel to. This may be a barrier for them accessing treatment.</p> <p>However, this would be offset by reducing the need to travel to hospital regularly for dialysis sessions.</p>	<p>The existence of a clear referral process into an MDT should enable access to the drug. The policy proposition will increase geographic access of providers of imlifidase enabled deceased donor kidney transplantation which is not currently available.</p> <p>If adopted, a commissioning plan will provide guidance for local service arrangements, which may include specialist oversight, to improve travel access for patients but with the necessary arrangements in place for reimbursement.</p>
<b>Refugees, asylum seekers or those experiencing modern slavery</b>	<p>Being a refugee, asylum seeker or experiencing modern slavery are not known to be risk factors for being highly sensitised.</p>	<p>The existence of a clear referral process into an MDT should enable access to the drug. The policy proposition will increase geographic access of providers of imlifidase enabled deceased donor</p>

Groups who face health inequalities <sup>2</sup>	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>Imlifidase enabled kidney transplantation will need to be done in specialist centres, which may be far for some patients to travel to. This may be a barrier for them accessing treatment.</p> <p>However, this would be offset by reducing the need to travel to hospital regularly for dialysis sessions.</p>	<p>kidney transplantation which is not currently available.</p> <p>If adopted, a commissioning plan will provide guidance for local service arrangements, which may include specialist oversight, to improve travel access for patients but with the necessary arrangements in place for reimbursement.</p>
<b>Other groups experiencing health inequalities (please describe)</b>	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	No <input checked="" type="checkbox"/>	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	This involves clinical staff, professional groups, patients, patient groups and industry groups who have expressed an interest in this topic area.	
2	Public consultation (planned)	This is not considered necessary for this commissioning statement.	

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
<b>Published evidence</b>	NICE imlifidase technology appraisal. Histocompatibility & Immunogenetics (H&I) de-listing guidelines. British Transplant Society imlifidase enabled kidney transplant guidelines. Scottish Medicines Consortium advice on imlifidase.	
<b>Consultation and involvement findings</b>	Completed by NICE	
<b>Research</b>	Completed by NICE	
<b>Participant or expert knowledge</b> For example, expertise within the team or expertise drawn on external to your team	The criteria of this policy have been informed largely by the clinical expertise of the PWG, NICE TA809 recommendation and the national Imlifidase MDT	

**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	
2	
3	

**10. Summary assessment of this EHIA findings**

This commissioning statement aims to provide equitable and appropriate access to imlifidase enabled kidney transplantation which is approved via the NICE TA809. It is not thought to adversely impact on any other individuals from protected characteristic groups. This would aim to reduce variation in access and ensure centres are all providing the same level of care.

**11. Contact details re this EHIA**

Team/Unit name:	NHS England, Specialised Commissioning
Division name:	Clinical Policy Team

Directorate name:	Chief Financial Officer
Date EHIA agreed:	
Date EHIA published if appropriate:	

## Internal decision-making not for external circulation

**12. Do you or your team need any key assistance to finalise this EHIA? Please delete the incorrect responses. If you require assistance please submit this EHIA and the associated proposal to EHIU (england.eandhi@nhs.net).**

<b>Yes:</b>	<b>No:</b>	<b>Uncertain:</b>
-------------	------------	-------------------

**13. Assistance sought re the completion of this EHIA:**

If you do need assistance to complete this EHIA, please summarise the assistance required below.
--

**14. Responsibility for EHIA and decision-making**

Contact officer name and post title:	Yasmin Stammers Senior manager, Internal medicine Programme of Care	
Contact officer e: mail address:	Yasmin.stammers@NHS.net	
Contact officer mobile number:		
Team/Unit name: Internal medicine PoC	Division name: Specialised commissioning	Directorate name: Chief Finance Officer
Name of senior manager/ responsible Director:	Post title:	E-mail address:

**15. Considered by NHS England or NHS Improvement Panel, Board or Committee<sup>3</sup>**

Yes:	No:	Name of the Panel, Board or Committee:		
<b>Name of the proposal (policy, proposition, programme, proposal or initiative):</b>				
Decision of the Panel, Board or Committee	Rejected proposal	Approved proposal unamended	Approved proposal with amendments in relation to equality and/or health inequalities	
Proposal gave due regard to the requirements of the PSED?		Yes:	No:	N/A:
Summary comments:				
Proposal gave regard to reducing health inequalities?		Yes:	No:	N/A:
Summary comments:				

**16. Key dates**

Date draft EHIA completed:	
Date draft EHIA circulated to EHIU: <sup>4</sup>	
Date draft EHIA cleared by EHIU: <sup>5</sup>	
Date final EHIA produced:	
Date signed off by Senior Manager/Director: <sup>6</sup>	
Date considered by Panel, Board or Committee:	
Date EHIA published, if applicable:	

<sup>3</sup> Only complete if the proposal is to be considered by a Panel, Board or Committee. If it will not be considered by a Panel, Board or Committee please respond N/A.

<sup>4</sup> If the team producing the proposal has important unresolved issues or questions in relation to equality or health inequalities issues, the advice of the EHIU should be sought. A draft EHIA must also be completed, and attached to the proposal, if the proposal is to be considered through NHS England and NHS Improvement's Gateway process.

<sup>5</sup> If the EHIU raises concerns about the proposal, the EHIA should state how these concerns have been addressed in the final proposal.

<sup>6</sup> The Senior Manager or Director responsible for signing off the proposal is also responsible for signing off the EHIA.

EHIA review date if applicable <sup>7</sup> :	
---	--

---

<sup>7</sup> This will normally be the review date for the proposal unless a decision has been made to have an earlier review date.