GIG CYMRU NHS WALES
Cyd-bwyllgor Comisiynu
Joint Commissioning Committee

# Imlifidase: desensitisation treatment option for adults who are awaiting a kidney transplant from a deceased donor

## Policy Position Statement: PPS256

| Document Information | |
|---|---|
| **Document Name** | Imlifidase: desensitisation treatment option for adults who are awaiting a kidney transplant from a deceased donor |
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| **Commissioning Team Author** | Welsh Kidney Network |
| **Target Audience** | Chief Executives, Medical Directors, Directors of Finance, Welsh Kidney Network Board, Welsh Transplant Clinical Reference Group, NHS England Providers, Medicines Manufacturer and patient groups |
| **Description** | NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy |

# Contents

# Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission imlifidase, which is a desensitisation treatment option for adults who are awaiting a kidney transplant from a deceased donor, in accordance with the criteria outlined in this document.

## Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the Welsh Language Act (1993), the Welsh Language (Wales) Measure 2011 and the Welsh Language Standards (No.7) Regulations 2018.

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

## Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment.

## Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority. NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

# 1. Introduction

This Policy Position Statement has been developed for the planning and delivery of imlifidase as a desensitisation treatment option for adult residents in Wales. This service will only be commissioned by the Welsh Kidney Network through the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

In creating this document NWJCC has reviewed the relevant guidance issued by the National Institute of Health and Care Excellence (NICE)[1] and has concluded that Imlifidase should be made available.

## 1.1 Background

In Wales there are approximately 1,400[2] adults who are dependent on dialysis to maintain life as a consequence of chronic kidney disease (CKD). Kidney transplantation is an alternative treatment option, although not all patients would be suitable. Some people who need a transplant have an immunological barrier to transplantation. They have antibodies to human leukocyte antigens (HLA), which is known as being 'sensitised'. This is because they have antibodies against almost all donors' HLA (known as a positive cross match). In these circumstances, the donor kidney would be at very high risk of antibody-mediated rejection and failure.

Highly sensitised patients are considered higher risk transplant recipients and wait longer to be offered a suitable match with a compatible deceased organ donor than non-sensitised (no HLA antibodies) patients as they must wait for donors that do not have the HLA antigens to which they have antibodies. Highly sensitised patients therefore require dialysis treatment for longer, which has a significant adverse effect on both quality and length of life.

In highly sensitised patients, imlifidase rapidly removes the majority of antibodies, including the HLA antibodies that would trigger immediate rejection from the patient immediately prior to receiving a deceased donor kidney transplant. Imlifidase is an enzyme that breaks down human immunoglobulin G (IgG) antibodies. This enables imlifidase to reverse a positive cross match and create a short period of time allowing transplantation to proceed.

[1] Overview | Imlifidase for desensitisation treatment before kidney transplant in people with chronic kidney disease | Guidance | NICE
[2] Quality statement for kidney disease [HTML] | GOV.WALES

## 1.2 Equality Impact Assessment

The Equality Impact Assessment (EIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

An EIA[3] was carried out by NICE during the evaluation of imlifidase. For further details, please refer to the NICE website at: NICE EIA Imlifidase.

[3] equality-impact-assessment-guidance-development

# 2. Recommendations

The recommendations below represent the views of NICE, arrived at after careful consideration of the evidence available. Health professionals are expected to take into account the relevant NICE guidance[4], alongside the individual needs, preferences and values of the patient.

Imlifidase will only be recommended if:

- a maximum of 1 dose is given
- it is given in a specialist centre with experience of treating high sensitisation to HLA
- the company provides imlifidase according to the commercial arrangement.

## 2.1 Inclusion Criteria[5]

Patients must meet all the following inclusion criteria to be eligible for imlifidase-enabled transplantation. The patient:

- is an adult (18 and above) and are waiting for a kidney transplant from a deceased donor[6]
- has had the appropriate level of workup as detailed within Annex ii 'Starting arrangements for all patients'
- satisfies all NICE criteria
  - Has a calculated reaction frequency (CRF) of at least 99%
  - Has a matchability score of 10 (or 9 if Blood Group AB)
  - Has been on the waiting list for a transplant for at least 2 years are highly sensitised to human leukocyte antigens (HLA)
- has a positive crossmatch (actual or predicted) with the donor and are unlikely to have a transplant under the available kidney allocation system (including prioritisation programmes for highly sensitised people).

The British Transplantation Society have produces 'UK Guidelines on imlifidase enabled decreased donor kidney transplantation'[7]. These should be read in conjunction with this Policy.

[4] Overview | Imlifidase for desensitisation treatment before kidney transplant in people with chronic kidney disease | Guidance | NICE
[5] NHS England 2304-imlifidase-treatment-commissioning-statement.pdf
[6] Imlifidase is not licensed for use in children. Access for post pubescent children may be considered in line with the criteria in NHS Wales Medicines for Children's policy
[7] UK GUIDELINE ON IMLIFIDASE ENABLED DECEASED DONOR KIDNEY TRANSPLANTATION - British Transplantation Society (bts.org.uk)

## 2.2 Exclusion Criteria

Patients who meet any of the following exclusion criteria are contraindicated from treatment with imlifidase:

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the Summary of Product Characteristics (SmPC) [8]
- ongoing serious infection
- thrombotic thrombocytopenic purpura (TTP). Patients with this blood disorder may be at risk of developing serum sickness
- inability to satisfy NICE criteria
- breast feeding or pregnancy

It is recommended that very careful and individualised consideration of risks versus benefits is undertaken in the following scenarios as they are viewed as relative contraindications:

- High (>50%) likelihood of early (within 1 year) graft loss due to non-immunological reasons. e.g., recurrent disease.
- Dependency on humanised monoclonal antibody therapy for organ or life-threatening disease. E.g., atypical Haemolytic Uraemic Syndrome needing eculizumab therapy.
- Current dependency on intravenous immunoglobulin (IVIg) for organ or life-threatening disease.

## 2.3 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

## 2.4 Designated Providers

| **Service Provider** | **Designated Centre** |
|---|---|
| Cardiff & Vale University Health Board | Nephrology and Transplant Department<br>University Hospital of Wales<br>Heath Park Way<br>Cardiff<br>CF14 4XW |

[8] Idefirix 11 mg powder for concentrate for solution for infusion - Summary of Product Characteristics (SmPC) - (emc) | 13155

| | |
|---|---|
| Liverpool University Hospitals NHS Foundation Trust | Royal Liverpool University Hospital<br>Prescot Street<br>Liverpool<br>Merseyside<br>L7 8XP |
| Birmingham NHS Foundation Trust | Queen Elizabeth Hospital<br>Mindelsohn Way<br>Birmingham<br>B15 2GW |

## 2.5 Patient Pathway (Annex i)

The patient pathway is shown in Annex i.

## 2.6 Starting arrangements for all patients (Annex ii)

The starting arrangements for all patients is shown in Annex ii.

## 2.7 Mechanism for funding

Imlifidase will only be funded for patients registered via the Blueteq® system and where an appropriately constructed MDT has approved its use within highly specialised centres.

Where the patient meets the criteria in this policy and the referral is received by an agreed centre, a Blueteq® form should be completed for approval. The Blueteq® form should be initiated at the point of when an identified patient is ready to be activated on the deceased donor transplant list.

For further information on accessing and completing the Blueteq® form please contact NWJCC using the following email address: NWJCCblueteq@wales.nhs.uk.

If a non-contracted provider wishes to treat a patient that meets the criteria they should contact NWJCC at NWJCCipc@wales.nhs.uk. They will be asked to demonstrate they have an appropriate MDT in place.

Funding is approved on the basis that imlifidase is prescribed and administered in accordance with its marketing authorisation[9] reference 13155, (for noting only one dose) of imlifidase is prescribed and administered as a powder for concentrate for solution for infusion. The company has a commercial arrangement, this makes imlifidase available to the NHS with a discount. The size of the discount is commercial in confidence. Health

[9] Idefirix 11 mg powder for concentrate for solution for infusion - Summary of Product Characteristics (SmPC) - (emc) | 13155

Boards in Wales should refer to the AWTTC Commercial Medicines Access References Tool (CMART) for further information on the Patient Access Scheme (PAS) price.

## 2.8 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

## 2.9 Action to be taken

- Health Boards and NWJCC are to circulate this Policy Position Statement to all Hospitals/MDTs to inform them of the conditions under which imlifidase will be commissioned.
- NWJCC are to ensure that all providers are purchasing imlifidase at the agreed discounted price.
- Providers are to ensure the need to approve imlifidase at the appropriate MDT and are registering use on the Blueteq® system, and the treatment will only be funded where the Blueteq® minimum dataset is fully and accurately populated.
- Providers are to determine estimated patients numbers and the current dose of any patient(s) who will transfer from any company compassionate use scheme EAMS.
- The Provider should work to written quality standards and provide monitoring information to NWJCC on request.

# 3. Putting things right

## 3.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to NWJCC.

## 3.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

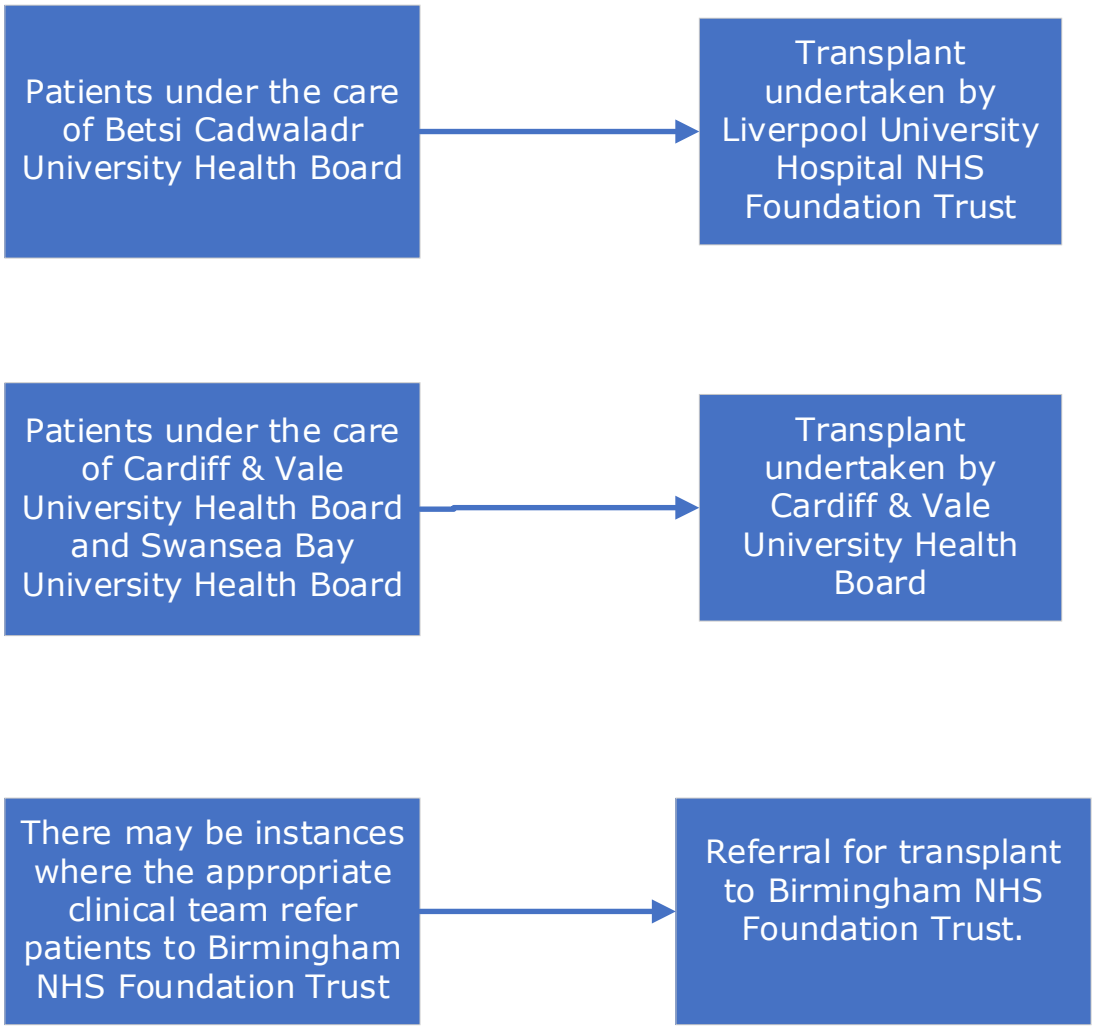
Further information on making IPFR requests can be found at: Individual Patient Funding Requests

# Annex i Patient Pathway

Patients under the care of Betsi Cadwaladr University Health Board will have their transplant undertaken by Liverpool University Hospital NHS Foundation Trust.

Patients who are under the care of Cardiff & Vale University Health Board and Swansea Bay University Health Board will have their transplant undertaken by Cardiff & Vale University Health Board.

There may be instances whereby patients may be referred to Birmingham NHS Foundation Trust, this would be determined by appropriate clinical team.



# Annex ii Starting arrangements for all patients

The guidance for treatment with imlifidase is covered by the NICE technology appraisal (TA809) on imlifidase-enabled deceased donor kidney transplantation.

**Starting criteria**

The patient must be discussed at a local MDT confirming they are medically fit to undergo an imlifidase-enabled kidney transplant. The MDT must include input and advice provided by a Consultant Clinical Scientist in Histocompatibility and Immunogenetics (H&I), given the high level of H&I laboratory testing and expertise required for successful transplantation. The patient must have the physiological reserve to withstand treatment burden including, if necessary, treatments for post-transplant severe Acute Cellular & Antibody Mediated Rejection.

- The patient must be carefully counselled, using appropriate patient information aids where necessary, regarding risks versus benefits of imlifidase-enabled transplantation and informed consent obtained prior to making changes to unacceptable antigen specificities.
- Consider offering relevant prophylactic vaccination prior to de-listing, including pneumococcal, meningococcal (tetravalent and sero-group B), Influenza and SARS-CoV-2 vaccines for patients eligible to receive imlifidase-enabled transplantation. Wherever possible, all relevant vaccinations are to be completed at least two weeks prior to the planned de-listing of unacceptable antigen specificities (UAGs).

**First Level Workup (Low / Intermediate Risk Transplant)**

In order for a patient to be considered for an imlifidase-enabled transplant, the following requirements need to be met:

- Historic positive specificities and previous repeat mismatched HLA antigens (organ transplant) should be de-listed if currently negative on single antigen beads assay. Include any specificities that have tested negative in three consecutive samples within the last 6 months or longer. For some patients, this step may not be achievable. If this is the case, move directly to second level workup.
- Try to achieve a minimum target of n/10,000 = 100 to attract donor offers.
- Review after 3-6 months and if no donor offers have been received, and no further specificities can be de-listed, proceed to imlifidase-enabled Transplant.

**Second Level Workup - (High Risk Transplant)**

In order for a patient to be considered for an imlifidase-enabled transplant, the following requirements need to be met:

- Unacceptable antigens should only be considered for de-listing after the corresponding HLA antibody profile has stabilised or is falling.
- Prioritise specificities for de-listing starting with weaker and progressing to stronger antibodies. Titration could be used for specificities at or close to the single antigen bead assay saturation point. If possible, delisting repeat mismatches with previous transplants should be avoided (see BTS guidelines).
- Where titration is used, prioritise the de-listing of specificities for which the MFI of the related antibody shows clear reduction upon dilution at 1:16 or lower. Aim to achieve n/10,000 *if possible* ≥100, but it is accepted that this may be difficult to achieve (a cautious lower number is acceptable but will clearly reduce the chance of an offer).

If this first stage does not generate donor offers, review the case and extend the de-listing process to include higher level antibodies.

- If possible, avoid multiple de-listed unacceptable antigens giving an unacceptably high cumulative MFI. If de-listing specificities that are in linkage disequilibrium, only de-list the specificity that is most frequently seen in the UK population. If this does not generate donor offers, add in additional specificities until n/10,000 is increased.
- All de-listings must be agreed by the local MDT before implementation.
- Review de-listed unacceptable antigens every 3 months (minimum) and continue to release additional specificities with increasing risk as outlined.

# Annex iii Codes

The list of ICD codes is indicative and is not exhaustive. Additional codes may be used for contract monitoring purposes, furthermore some codes may cover indications not included within this policy.

| Code Category | Code | Description |
|---|---|---|
| | Y83.0 | Surgical operation with transplant of whole organ |
| | Z94.0 | Kidney transplant status |
| | N18.5 | Chronic kidney disease, stage 5 |

# Contact Us

If you have a question related to this document you can contact us using one of the methods outlined below.

If you would like this document in an alternative format and/or language, please contact us for assistance.

**Email:**

NWJCC consultation mailbox – nwjccconsultation@wales.nhs.uk

**Telephone:**

General Enquiries – 01443 433112

**Website:**

Contact us - NHS Wales Joint Commissioning Committee

**Writing:**

If you wish to contact the NHS Wales Joint Commissioning Committee, you can write to us at one of our locations below, we welcome correspondence in Welsh or English:

**South Wales Offices**
Unit 1, Charnwood Court, Heol Billingsley, Nantgarw, CF15 7QZ
Unit G1 The Willowford, Main Avenue, Treforest Industrial Estate, Pontypridd, CF37 5YL

**North Wales Offices**
Unit 3, Media Point - Unit 3, Mold Business Park, Mold, CH7 1XY
Preswylfa, Hendy Road, Mold, CH7 1PZ