

## **Changes in this version**

Section 2.1 - Additional rule where reallocation applies where the centre has accepted an offer for a recipient receiving Imlifidase

## **Policy**

This policy has been created by the Kidney Advisory Group on behalf of NHSBT.

*This policy previously received approval from the Transplant Policy Review Committee (TPRC). This committee was disbanded in 2020 and the current governance for approval of policies is now from Organ and Tissue Donation and Transplantation Clinical Audit Risk and Effectiveness Group (OTDT CARE), which will be responsible for annual review of the guidance herein.*

*Last updated: February 2023*

*Approved by OTDT Care: February 2023*

The aim of this document is to provide a policy for the allocation and acceptance of deceased donor organs to adult and paediatric recipients on the UK national transplant list. These criteria apply to all proposed recipients of organs from deceased donors.

In the interests of equity and justice all centres should work to the same allocation criteria.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the *Non-Compliance with Selection and Allocation Policies*.

<http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/>

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, mechanisms are in place for the allocation of organs in exceptional cases.

Kidneys from deceased donors whose death has been defined by brain-stem death criteria (DBD donors) or by circulatory death (DCD donors) are allocated through a National Allocation Scheme.

This policy predominantly covers kidney only transplantation. Multiple organ transplantations are covered in section 3.

## **1. Allocation policy**

### **1.1. How allocation policy was developed**

A new kidney offering scheme has been introduced in the UK to reflect the changing donor pool and to address some of the inequities observed in the previous scheme (introduced in 2006<sup>1,2</sup>). The new scheme will allocate all kidneys from both DBD and DCD donors and will more effectively match graft life expectancy with patient life expectancy.

#### **1.1.1. Kidneys from deceased donors**

All kidneys from deceased donors are offered through the national offering scheme, managed by NHSBT.

The left kidney is offered to the highest ranked patient on the kidney matching run. Only a centre allocated a kidney for a paediatric patient (under 18 years of age) or patient in Tier A can request the other kidney based on anatomy, damage, pathology, or perfusion quality.

If a donor is identified as having a “horseshoe kidney” at registration then it will be offered as one kidney. If this is identified at retrieval then the decision to split or remain as one kidney will be made by the retrieval surgeon and the implanting surgeon at the centre with the highest ranking recipient.

#### **If the donor HLA-type is not known at the time of offering**

This is likely to be extremely rare for kidneys from DBD donors but may be more common for kidneys from DCD donors. If the donor HLA type is not known at the time of offering, one kidney will be offered via the kidney matching run to the local centre and then centres with the highest ranked patients listed although the centre may transplant the kidney in to any locally listed patient. One kidney will be offered with the pancreas via the Pancreas Fast Track Scheme. If no offer is accepted within 45 minutes OR if at any stage the pancreas is accepted for pancreas or pancreatic islet only transplantation, the kidney will be offered back to centres via the kidney matching run.

### **1.2. Allocation scheme principles**

#### **1.2.1. Patient prioritisation**

All kidneys from deceased donors to be allocated via an evidence-based computer algorithm unless the donor is classed as D4 and aged over 70. This is based on two ranked Tiers of recipients who are eligible (as defined below) to receive a particular donor’s organs:

Tier A	Patients with matchability score = 10* or Patients with 100% calculated reaction frequency* or Patients that have accrued 7 years of waiting time
Tier B	All other eligible patients

\*(based on comparison with pool of 10,000 donor HLA types on national database)

Tier A includes kidney only, simultaneous kidney/pancreas (SPK) and simultaneous kidney/islet (SIK) patients meeting the criteria. Patients waiting for a SPK or SIK are eligible to accept the offer of a kidney only. Within Tier A, patients are prioritised according to matchability score and waiting time.

Tier B includes kidney only patients. Within Tier B, patients are prioritised according to a points-based system (highest score first), based on 8 elements, these include:

- Waiting time from earliest of start of dialysis or activation on the list

- Donor-recipient risk index combinations
- HLA match and age combined
- Location of patient relative to donor
- Matchability
- Donor-recipient age difference
- Total HLA mismatch
- Blood group match

**Waiting times**

Number of days waiting time accrued.

Waiting time is determined from date of starting permanent dialysis (HD or PD) or date of first active listing for a graft, whichever is earliest. Each day accrues 1 point, including all days of suspension from the list.

Any patient whose previous graft failed within the first 180 days post-transplant starts with a waiting time as it was on the day of that (failed) transplant. The failure must be reported to NHSBT through a follow-up return to enable the waiting time to be calculated accurately.

Waiting time is transferable when a patient transfers from one transplant centre to another, and the centre must confirm changes in writing by sending an email to [ODTRegistrationTeamManagers@nhsbt.nhs.uk](mailto:ODTRegistrationTeamManagers@nhsbt.nhs.uk). The time will be calculated automatically provided the patient has not been 'removed' from the list as part of the transfer.

**Donor-recipient risk index combinations**

A donor risk score (DRI) is calculated for each donor on offer using 7 risk factors. A donor is then categorised in to one of 4 groups based on the risk score and by pre-determined cut-off values. D1 (lowest risk), D2, D3 and D4 (highest risk).

$$\begin{aligned}
 \text{DRI} = \exp \{ & 0.023 \times (\text{donor age}-50) & + \\
 & -0.152 \times ([\text{donor height}-170]/10) & + \\
 & 0.149 \times (\text{history of hypertension}) & + \\
 & -0.184 \times (\text{female donor}) & + \\
 & 0.190 \times (\text{CMV +ve donor}) & + \\
 & -0.023 \times ([\text{offer eGFR}-90]/10) & + \\
 & 0.015 \times (\text{days in hospital}) & \}
 \end{aligned}$$

D1	≤ 0.79
D2	0.79 – 1.12
D3	1.12 – 1.50
D4	≥1.50

A recipient risk score (RRI) is calculated, for each eligible patient using 4 risk factors. A recipient is then categorised in to one of 4 groups based on the risk score and by pre-determined cut-off values. R1 (lowest risk), R2, R3 and R4 (highest risk).

$$\begin{aligned}
 \text{RRI} = \exp \{ & 0 \times (\text{recipient age} \leq 25) - 75) & + \\
 & 0.016 \times ((\text{recipient age} > 25) - 75) & + \\
 & 0.361 \times (\text{recipient on dialysis at registration}) & + \\
 & 0.033 \times ([\text{waiting time from dialysis}-950]/365.25) & + \\
 & 0.252 \times (\text{Diabetic recipient}) & \}
 \end{aligned}$$

R1            ≤ 0.74  
 R2            0.74 - 0.94  
 R3            0.94 – 1.20  
 R4            ≥1.20

**Points are defined as:**

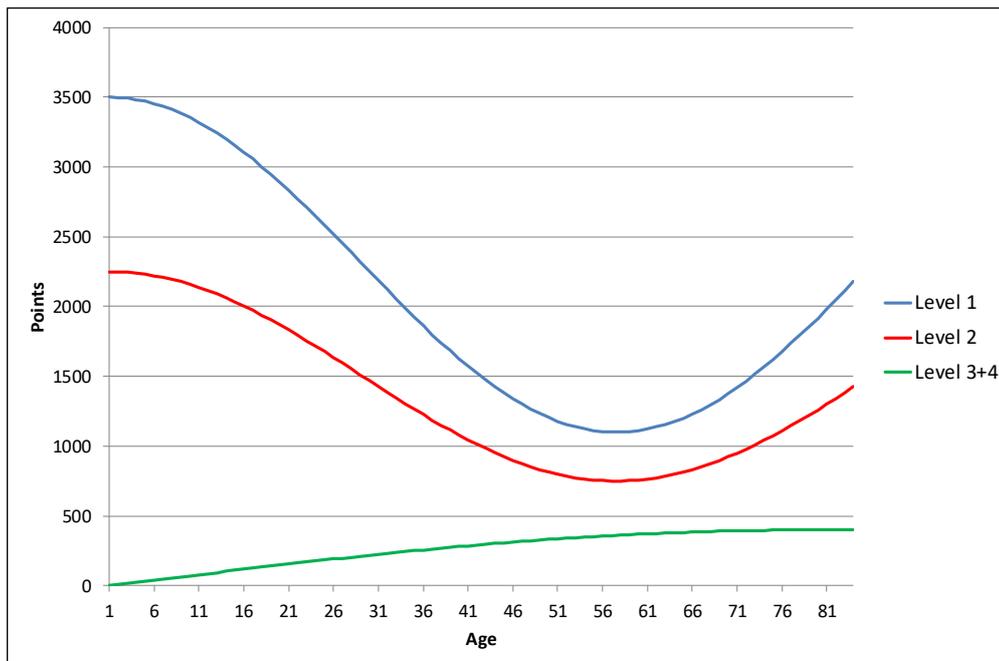
Donor Risk group	Recipient Risk Group			
	R1	R2	R3	R4
D1	1000	700	350	0
D2	700	1000	500	350
D3	350	500	1000	700
D4	0	350	700	1000

***HLA match and age combined***

Points are defined as

- Level 1 =             $1200 * \text{COS}(\text{age}/18) + 2300$
- Level 2 =             $750 * \text{COS}(\text{age}/18) + 1500$
- Level 3+4 =         $400 * \text{SIN}(\text{age}/50)$

Points scored are illustrated below, and mismatch levels are shown in Table C



**Location of patient relative to donor**

Each donor hospital will be allocated to one of four regions, based on their designated centre as follows:

North	Midlands	South West	London
Edinburgh	Birmingham	Bristol	GOSH
Glasgow	Cambridge	Cardiff	Guy's
Leeds	Coventry	Oxford	The Royal Free
Liverpool	Leicester	Plymouth	The Royal London
Manchester	Nottingham	Portsmouth	St George's
Newcastle	Sheffield		WLRTC
	Belfast		

Points are allocated based on the location of the potential recipient as follows:

For donors after brain death:

- Within region = 500 points
- Within centre = 500 points

For donors after circulatory death:

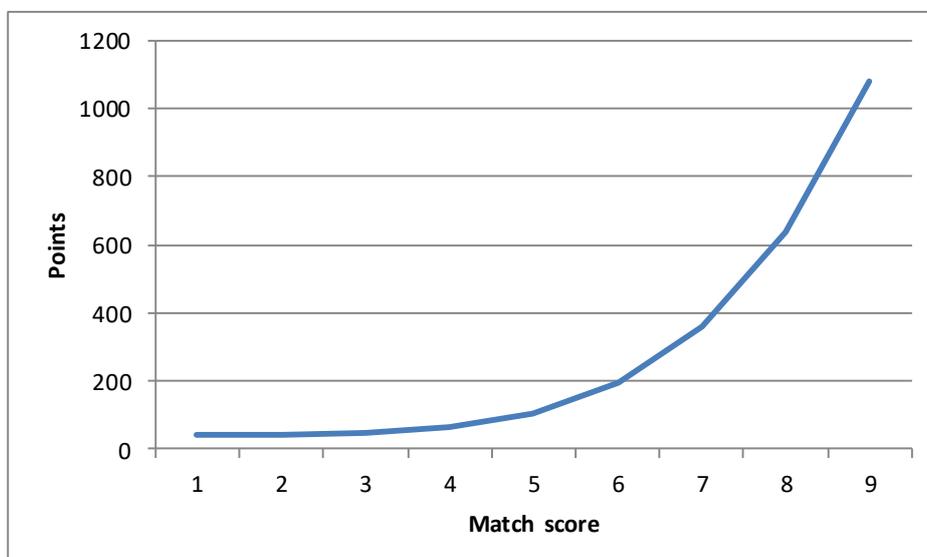
- Within region = 1000 points
- Within centre = 1250 points

**Matchability**

Points are defined as:

$$40 * (1 + (\text{Match score} / 4.5)^{4.7})$$

Points scored are illustrated below



**Donor–recipient age difference**

Age difference points =  $-\frac{1}{2} (\text{donor}-\text{recipient age difference})^2$

For example, for a donor aged 60 and a potential recipient aged 20, 800 points are subtracted from the points total for the potential recipient.

**Total HLA mismatch**

A total mismatch score is calculated based on the number of mismatches at HLA-A, B, Cw, DR and DQ.

Total HLA mismatch = 0	0 points
Total HLA mismatch = 1	-100 points
Total HLA mismatch = 2-3	-150 points
Total HLA mismatch = 4-8	-250 points
Total HLA mismatch = 9-10	-500 points

**Blood group match**

-1000 points are allocated for blood group B patients when the donor is group O (Tier B only).

**D4 donors aged 70 and over**

To optimise the utilisation rate of higher risk older donor kidneys available for transplantation, both kidneys from donors categorised as D4 and 70 years or older will be offered as dual kidneys to the centre with the highest patient listed (according to the National Kidney Offering Scheme) although that centre may transplant the kidney(s) in to any locally listed patient. In some situations only one kidney may be available (for example, if one of the kidneys is allocated as part of a multi-organ transplant) and in this case the remaining kidney would be allocated in the same way as the dual kidneys.

**1.2.2. Patient eligibility criteria**

Eligibility criteria are primarily based on blood group and HLA match between donor and potential recipient.

**Blood group eligibility**

Patients with blood groups incompatible with the donor’s blood group (as defined in Table A) are not eligible to receive that donor’s organs. There are restrictions on blood group-compatible (but not blood group identical) patients, detailed in Table A.

Table A		Donor – recipient blood group matching policy			
Donor	Recipient				
	O	A	B	AB	
O	✓	✓*	✓	✓*	
A		✓		✓	
B			✓		
AB				✓	

\* Tier A only

***HLA match eligibility***

Donors are HLA-typed at the local H&I laboratory according to the minimum resolution specification agreed by the NHBST Kidney Advisory Group and are reported to Hub Operations by secure email.

Patients with HLA types that are not compatible with the donor’s HLA type are not eligible to receive that donor’s organs. Recipient antibodies reported at the HLA-A, B, Cw, DR, DP and DQ loci are considered. For a patient changing transplant centre, any incoming registration that does not contain one or more of the unacceptable antigens already recorded for a patient will be checked with the tissue typing laboratory to ensure a patient isn’t disadvantaged.

The HLA match between donor and recipient is determined on the basis of the HLA-A, B, and DR loci only (although match at HLA- Cw and DQ is also calculated for points score). The numbers of unique, broad level donor antigens not present in the recipient are counted to determine the HLA mismatch and mismatch level upon which points are based. This is done on the basis of defaulting rare HLA specificities to more common equivalents. The rare antigens and equivalents that are considered are shown in Table B.

The rare specificities indicated are defaulted to their more common equivalents so that patients with rare tissue types match with more donors. The defaults are applied (as appropriate) at NHSBT as part of the allocation algorithm. This enables patients with rare specificities also to be considered a match should a donor with the same rare specificities become available.

HLA mismatch grades are determined and then categorised as shown in Table C. Patients with a level 4 HLA mismatch with the donor are not eligible to receive the donor’s organs through the national allocation scheme if the recipient has a matchability score 7 or less.

<b>Table B Defaulting of rare HLA specificities</b>	
<b>Rare specificity</b>	<b>Common equivalent</b>
A36	A1
A80	A1
A43	A10
B53	B5
B41	B40
B42	B7
B46	B15
B47	B27
B48	B40
B59	B8
B67	B22
B70	B35
B73	B7
B78	B35
B81	B7
B82	B12
B83	B12
DR103	DR1

DR10	DR1
DR9	DR4
DR11, DR12	DR5

<b>Table C HLA mismatch levels for HLA-A, B and DR</b>		
<b>Level</b>	<b>HLA mismatch summary</b>	<b>HLA mismatch combinations included</b>
1	000	000
2	[0 DR and 0/1 B] or [1 DR and 0 B]	100, 010, 110, 200, 210, 001, 101, 201
3	[0 DR and 2 B] or [1 DR and 1 B]	020, 120, 220, 011, 111, 211
4	[1 DR and 2 B] or [2 DR]	021, 121, 221, 002, 102, 202, 012, 112, 212, 022, 122, 222

**1.2.3. Additional considerations for paediatric patients**

**Older donors**

Paediatric patients and young adults (<18 years at time of active listing) will not be considered for kidneys from donors over 60 years of age.

**Clinically urgent paediatric patients**

A child may be priority listed for the next eligible blood group compatible donor, aged 60 years and under, regardless of match grade, in the following situations:

- In the event of potential imminent or actual loss of dialysis access without which the child will not survive
- In a child
  - With functioning dialysis but no alternative dialysis access
  - And where dialysis access is likely to become difficult within a short period
  - And when special restrictions are required for a suitable kidney - (e.g. size due to anatomical difficulties in the recipient), which significantly restricts the possibility of an appropriate donor
- Options for live related donation have been excluded

Before a child is priority listed an independent review should be carried out by two clinicians from different transplant centres to where the child is listed.

**1.2.4. Allocation of kidneys donated in a domino procedure<sup>3</sup>**

In these cases, local allocation is appropriate, and the kidney should be allocated in advance to a local recipient through Hub Operations at NHSBT.

Local allocation is deemed appropriate because:

- Domino donation is uncommon and equity of access to kidney transplantation is unlikely to be affected by local allocation
- Local allocation provides a better environment for managing the uncertainty associated with domino donation and potentially facilitates improved patient and graft outcomes

## **2. Acceptance of offered kidneys**

The receiving centre will undertake HLA cross-matching according to their local policy (based on BTS guidelines).<sup>4</sup> All HLA typing, and cross-matching must be undertaken in premises which hold ISO 15189 accreditation for these tests.

### **2.1. Reallocation of kidneys**

If a kidney needs to be reallocated because the patient for whom the kidney has been accepted cannot subsequently receive the transplant, the following rules apply:

- If the kidney has not been dispatched to the transplant centre it will continue to be offered for prioritised patients in the usual way
- If the kidney has been dispatched to the transplant centre, it will be offered back for any patients in Tier A. If there are no suitable patients (nationally or regionally as appropriate), the kidney can be kept by the centre to which the kidney has been dispatched. The centre will select the most appropriate patient from their local list.
- If the accepted offer is for a recipient receiving lmlifidase, the centre should ask the Hub for a backup recipient. If lmlifidase has been administered and the transplant cannot go ahead then the kidney can be offered to the backup recipient.

Note that when selecting a patient of their own choice, a centre may, in exceptional circumstances, select a patient with a level 4 HLA match or a patient who is blood group compatible but falls outside of the blood group matching criteria specified.

### **2.2. The Kidney Fast Track Scheme**

To optimise the utilisation rate of kidneys available for transplantation a Kidney Fast Track Scheme (KFTS) was introduced for DBD donors on 1 December 2012 and for DCD donors on 1 March 2013.

#### **2.2.1. Kidney Fast Track Scheme offering criteria for DBD donor kidneys**

Kidneys from DBD donors will be offered through the Fast Track Scheme if any of the following criteria are met:

- If, at any point, the kidney is deemed to be unusable by a SNOD or a member of the retrieving or transplanting team.
- Seven kidney transplant centres decline a kidney-only offer for either donor or organ quality reasons. The reasons given may differ between centres but must relate specifically to the donor or organ quality.
- The organ has accrued six hours of cold ischaemia time and has not yet been accepted for transplantation, or in the case of *kidneys that are first offered and accepted as part of a multi-organ transplant (e.g. simultaneous pancreas/kidney, simultaneous islet/kidney or liver and kidney)*, the kidney should not be Fast-Tracked until the organ has accrued 12 hours of cold ischaemia time.

#### **2.2.2. Kidney Fast Track Scheme offering criteria for DCD donor kidneys**

Kidneys from DCD donors will be offered through the Fast Track Scheme if any of the following criteria are met:

- If, at any point, the kidney is deemed to be unusable by a SNOD or a member of the retrieving or transplanting team.
- Seven kidney transplant centres decline the kidney for either donor or organ quality reasons. The reasons given may differ between centres but must relate specifically to the donor or organ quality.

- The organ has accrued three hours of cold ischaemia time and has not yet been accepted for transplantation, or in the case of *kidneys that are first offered and accepted as part of a multi-organ transplant (e.g. simultaneous pancreas/kidney, simultaneous islet/kidney or liver and kidney)*, the kidney should not be Fast-Tracked until the organ has accrued 6 hours of cold ischaemia time.
- If the kidney has been offered and accepted for transplantation but is **subsequently** declined by the accepting centre after treatment withdrawal **but before organ retrieval has begun**.

### **2.2.3. Offering via the Kidney Fast Track Scheme**

Centres must 'opt-in' to receive offers of kidneys through the KFTS. To qualify, centres must provide NHSBT with a 24-hour single SMS number and have access to the Electronic Offering System.

When a kidney from a deceased donor meets the Fast Track Scheme criteria, the organ will be offered simultaneously to each of the kidney transplant centres that have opted-in to the scheme. Each centre has 45 minutes, from the time of offer, to confirm whether or not they would like to accept the kidney. Failure to respond within the 45-minute window is equivalent to a declined offer. The fast-tracked kidney will be allocated to the accepting centre with the highest priority patient listed (according to the National Kidney Allocation Scheme) although that centre may transplant the kidney into any locally listed patient. Upon inspection, if the accepting centre decides the kidney is unusable, it will be offered to the accepting centre with the second highest priority patient listed and so on, until either the kidney has been transplanted or all accepting KFTS centres have declined the offer of the organ. Organs from deceased donors in Gibraltar will be facilitated using the same donor characterisation process as a UK donor and all information can be viewed on EOS. Due to the logistical issues encountered with a 3-hour flight time, these organs will be offered simultaneously to every centre who has registered to receive fast track offers. At the end of 45 minutes, organs will be allocated using previously agreed policy.

### **2.2.4. If the donor HLA is not known at time of Fast-Track offering**

This is likely to be extremely rare for kidneys from DBD donors but may be more common for kidneys from DCD donors. If the donor HLA type is not known at the time of Fast-Track offering a kidney matching run can still be produced to determine which of the accepting centres had the highest ranked recipient listed.

## **2.3. Blood-borne Positive Donor Virology Scheme**

To reduce the length of the donation process the positive donor virology scheme was introduced.

### **2.3.1. Positive donor virology scheme offering criteria for deceased donor kidneys**

The positive donor virology scheme is initiated when NHSBT is notified that a donor has an initial positive result for any of the markers listed below:

- Hepatitis B surface antigen (**not Hepatitis B** core antibody positive alone, with negative HBsAg)
- Hepatitis C antibody
- HIV 1 and 2 antibody
- HTLV 1 and 2 antibody

### **2.3.2. Offering via the positive donor virology scheme**

Centres must 'opt-in' to receive offers of kidneys through the positive donor virology scheme. When a kidney from a deceased donor meets the positive donor virology criteria, the organ will be offered simultaneously to each of the kidney centres that have opted-in to the scheme. Each centre has 45 minutes, from the time of offer, to confirm whether or not they would like to accept the kidney. Failure to respond within the 45 minute window is equivalent to a declined offer. The kidney

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will be allocated to the accepting centre with the highest priority patient listed although that centre may transplant the kidney in to any locally listed patient. Upon inspection, if the accepting centre decides the kidney is unusable, it will be offered to the accepting centre with the second highest priority patient listed and so on, until either the kidney has been transplanted or all accepting centres have declined the offer of the organ.

### **3. Allocation policies for multiple and paired organs**

#### **3.1. Prioritisation of patients requiring a kidney/pancreas or islet/kidney transplant**

These patients will be prioritised after Tier A kidney patients (i.e. after 100% cRF, matchability 10 or long waiting (>7 years) patients) for all DBD and DCD donor kidneys.

#### **3.2. Allocation of en bloc kidneys**

Kidneys from donors aged 4 years and under 365 days (before their 5<sup>th</sup> birthday) will be retrieved and offered *en bloc* (but may be split if appropriate) while kidneys from donors aged 5 years and over will be retrieved and transplanted singly wherever possible.

*En bloc* kidneys from donors aged 2 to 4 (i.e. before the 5<sup>th</sup> birthday) will be offered on a centre rather than patient basis to any centre wishing to receive offers of such kidneys.

*En bloc* kidneys from donors under 2 years of age will be offered to St James Hospital Leeds and Guys Hospital, London in the first instance; if both centres decline the kidneys they will be offered through the fast track scheme.

Kidneys will not be offered from donors under 1 month old, including neonates.

### **4. Special prioritisation for patients listed for kidney-only transplantation**

A patient identified to have missed an offer of a kidney due to a data or administrative error may be awarded special prioritisation in subsequent kidney matching runs. Prior to awarding special prioritisation, approval is required in writing from either the Chair of the Kidney Advisory Group or the Associate Medical Director for ODT NHSBT.

A patient awarded special prioritisation may be ranked above all other non-prioritised patients within their qualifying tier/level (Tier A and B), of the standard donor kidney matching run. Clinically urgent children and all other higher tiered patients will continue to be ranked higher than a special prioritised patient. Where two or more patients are awarded special prioritisation within the same matching run, they will be ordered first by their qualifying Tier and then by their matching run points score.

Special prioritisation will only be applied until one of the following events occurs:

- The patient receives a single offer of a kidney from an appropriately blood group and HLA matched donor, even if that offer is subsequently declined
- The recipient is successfully transplanted
- The recipient is removed from the kidney transplant list

### **5. Additional waiting time points for patients listed for kidney-only transplantation**

A patient identified as having fewer kidney waiting time points than they are entitled to (e.g. due to an administration error within the registration process) may be entitled to additional kidney waiting time points as compensation. Prior to awarding additional waiting time points, approval is required from either the Chair of the Kidney Advisory Group or the Associate Medical Director for ODT NHSBT.

If the patient is known to have missed an offer of a kidney as a result of an administrative error the patient may additionally be awarded special prioritisation described in **Section 4**.

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## **6. Exemption request process**

If a clinician considers that a transplant candidate is unfairly disadvantaged by the national allocation process, they may lodge an exemption request to be considered by the Kidney Advisory Group Exemptions Panel.

- 6.1.** The Exemptions Panel will be chaired by the Chair of the Kidney Advisory Group or deputy. The panel will consist of the Chair, his deputy, one representative from each of the four kidney allocation regions and one lay member.
  - 6.1.1.** Where the candidate's consultant is either the Chair or the nominated representative, then an alternate member must be identified, from a different hospital.
- 6.2.** The exemption request will be made by electronic means to the Statistical Lead who will circulate, within one working day, the members of the Exemptions Panel who must respond within three working days.
- 6.3.** The Chair will decide whether a teleconference is needed.
- 6.4.** The decision will be made by majority vote and the Chair will have a casting vote.
- 6.5.** The decision may be to decline the request or to award additional points.
- 6.6.** The outcome of every request will be presented to the next meeting of the Kidney Advisory Group.
- 6.7.** The candidate's consultant may appeal to the Associate Medical Director and the appeal considered at the next meeting of the Solid Organ Advisory Group Chairs Committee.

## **References**

- 1.** Johnson RJ *et al.* Factors influencing outcome after deceased heart beating donor kidney transplantation in the United Kingdom: an evidence base for a new national kidney allocation policy. *Transplantation* 2010;27:379–86.
- 2.** Johnson RJ *et al.* A new UK 2006 kidney allocation scheme for deceased heart beating donor kidneys. *Transplantation* 2010;27:387–94.
- 3.** Kidney Advisory Group. Allocation of kidneys donated in a domino procedure, 25<sup>th</sup> May 2011.
- 4.** British Society for Histocompatibility and Immunogenetics/British Transplantation Society document for guidelines on the detection and characterisation of HLA antibodies in renal transplantation. [https://bts.org.uk/wp-content/uploads/2016/09/06 BTS BSHI Antibodies-1.pdf](https://bts.org.uk/wp-content/uploads/2016/09/06_BTS_BSHI_Antibodies-1.pdf)