

## **Meeting Summary**

# OPTN Kidney and Pancreas Transplantation Committees Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary April 18, 2023 Conference Call

Valerie Chipman, RN, BSN, Chair

#### Introduction

The OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup (The Workgroup) met via Citrix GoTo teleconference on 4/18/2023 to discuss the following agenda items:

- 1. Dual Kidney: Carry Over Refusals
- 2. Kidney Minimum Acceptance Criteria (KiMAC)

The following is a summary of the Workgroup's discussions.

#### 1. Dual Kidney: Carry Over Refusals

Staff provided a recap the concept of carry over refusals and how they could work for dual kidney match runs as part of the transition to a continuous distribution framework. The Workgroup then reviewed and discussed specific carry over refusal codes that would be appropriate for a dual kidney match run.

#### **Presentation summary:**

Previously, the Workgroup discussed carrying over refusals as part of the solution for both released organ and dual kidney. In these cases, specific refusal codes would be "carried over" to the new match run (released organ or dual kidney). Meaning, candidates who have refused for specific, appropriate reasons would be screened from the released organs or dual kidney match run. The OPO would need to select which match run to carry refusals over from, in case multiple kidney matches are run. The focus of this meeting is to continue discussing carry over refusals for dual kidney. Previously, the Workgroup recommended that programs should be able to indicate whether they would accept an offer as dual for each candidate. Additionally, the Workgroup supported the following framework for dual kidney allocation:

- 1. In order to offer kidneys as dual, the host OPO would need to run a new, dual-specific match run
- 2. Specific criteria dictates when an OPO may begin allocating the kidneys as dual kidneys

The dual-kidney match run includes several efficiency considerations:

- Match run includes only candidates opted in to receive dual kidney offers
- Offer filters model takes dual kidney into account, and programs can build dual kidney specific filters
- Other screening tools, such as acceptance criteria and the kidney minimum acceptance criteria (KIMAC) tool, will also apply to the dual kidney match run
- Specific refusals will be carried over from the original match run to the dual kidney match run

Just like Released Organs, specific refusal codes would be "carried over" to the dual kidney match run

• Candidates whose transplant programs have refused the single kidney offer per a qualifying refusal reason would be screened from the dual kidney match run

- The organ procurement organization (OPO) would need to select which match run to carry refusals over from, in case multiple kidney matches are run
- OPOs would not be able to carry over refusals from system-locked matches, such as matches run before positive Hepatitis C (HCV) or Hepatitis B (HBV) results

Because a dual kidney offer is very different from a single kidney offer, most refusal reasons may not be appropriate to carry over to a dual kidney match run. Programs may be more willing to accept a dual kidney offer than a single kidney offer from medically complex donors. However, since the offer is still from the same donor, there may be certain refusal codes that are appropriate to carry over.

Previously, the Workgroup recommended that programs should be able to decline for a future dual kidney match at the time of the initial, single kidney offer and discussed adding this functionality to the OPTN Computer System. The recommendation for the first iteration of continuous distribution is to leverage the existing "donor refusal" functionality within the system and make improvements where necessary.

Staff explained the existing functionality of the donor refusal button, which allows programs to refuse current and future offers for a specific donor for all candidates for certain donor-specific codes by organ type. Programs will be able to decline the single kidney for specific candidates and have those refusals carry forward to the dual match via the proposed new functionality to carry over refusals. If a transplant program wants to decline for all candidates on a future kidney match, the recommendation is to use the donor refusal functionality. Staff asked members if separating "dual kidney" out as an organ checkbox would help encourage use of the tool, and if reworking the name "donor refusal" as well as the text description make the functionality clearer.

#### Summary of discussion:

A member stated that having a separate dual kidney organ type would make sense because dual kidney will also be split out into its own match run. An attendee agreed, and stated that acceptance practices vary based on the organ type, and that it would make more sense to have donor refusal at the organ level. A member stated that it should be clear to users whether the offer is dual or single on the refusal button. A member asked if members would have to decline for dual, and stated that they do not envision programs proactively clicking to decline for dual offers, and suggested creating a pop up to incentivize programs to make a decision. A member stated that utilizing carry over refusals helps keep the volume of offers to programs limited to only those that they would consider. One member agreed but stated that programs may not decline for dual unless they are specifically given that option. Staff thanked members and attendees for their feedback and will work to incorporate these insights into the donor refusal functionality.

A member asked if donor refusal is a current functionality, and staff noted that it is and that the button only appears when a program declines for a donor related reason. Another member stated that they have seen the button, but they prefer to enter in individual refusal codes.

Staff asked if members would like to recommend to incorporate the refusal functionality for donor related refusals for dual kidney, and members agreed. Staff asked if the Workgroup would like to recommend that the other potential refusal codes be carried over to the dual kidney match run. A member asked if the other codes are not limited to donor related refusals, and staff noted that yes, there are other refusal codes that may be appropriate to carry over, and that this would be what the Workgroup would ultimately recommend. An attendee stated that carrying over certain refusals makes sense from an efficiency standpoint, and a member agreed.

The Workgroup then reviewed and discussed specific carry over refusal codes that would be appropriate for a dual kidney match run, as described in the table below. Additionally, Workgroup members reviewed the carryover refusal codes ahead of the meeting and submitted thoughts on what should or should not be carried over. A member stated that it would be best to have the codes that are carried over be as conservative as possible, to allow program choice and discretion. The specific codes are found within the OPTN Computer System.

Code	Refusal Reason	Description	Workgroup Notes	Carry Over?
	Donor and Candidate Matching			
700	Donor age	Donor age is not clinical suitable for PTR		N
701	Organ size, specify**	Donor organ expected to be too large or small for PTR		N
	Organ Specific			
710	Organ preservation: unacceptable method or findings	Method or findings of organ preservation does not meet acceptable criteria (pump pressures, pumping issue, not pumped, on pump, etc.).		N
711	Organ anatomical damage or defect	Surgical damage, non-surgical trauma, diseased organ, organ vasculature, en bloc kidneys or any other anatomical reason	Some injuries may be mitigated by receiving the second kidney	N
712	Actual or projected cold ischemic time too long	The actual or projected cold ischemic time is too long for the organ	More nephron mass may mitigate damage from cold ischemic time.	Z
713	Warm ischemic time too long	The warm ischemic time is too long for the organ		N
714	Biopsy not available	Organ biopsy results are not available or a biopsy was not performed		N
715	Biopsy results unacceptable	Organ biopsy results do not meet acceptable criteria		N
716	Organ specific test results not available, specify**	Organ specific test not done or results not available at time of organ offer (e.g. HIC NAT testing, cardiac catheter results, etc.) Do not use for unavailable biopsies	Some tests could come back later, or other test results may be mitigated by receiving two kidneys. Workgroup members noted that they were unsure how often this code is used.	N

Code	Refusal Reason	Description	Workgroup Notes	Carry Over?
717	Unacceptable organ specific test results, specify *	Organ specific test results do not meet acceptable criteria (e.g., lowPaO2, high creatinine, low ejection fraction, or imaging findings). Do not use for biopsy results that are unacceptable.		N
	Candidate Specific			
720	Candidate temporarily medically unsuitable	Potential recipient temporarily too sick, medically contraindicated, or not optimized to attempt transplant	Members noted that this would likely still be the case at the time of the dual offer.	Y
721	Candidate transplanted or pending transplant	PTR has been transplanted, a transplant is in progress, or another offer is being considered	Members noted that this should not be carried over, in case a candidate had an offer or transplant that fell through, though this would be rare.	N
722	Candidate's condition improved, transplant not needed	PTR's condition has improved and transplant is currently unnecessary	Members noted that this would likely still be the case at the time of the dual offer.	Y
723	Candidate requires different laterality	PTR requires organ of a different laterality (e.g. right lung is specified)	Members noted that this code does not typically apply to kidney and may have been used by mistake.	N
724	Candidate requires multiple organ transplant	PTR requires a multiple organ transplant (e.g. heart offered without kidney)	Unlikely to be resolved at the time of the dual offer.	Y
725	Epidemic/Pandemic – Candidate	PTR related epidemic/pandemic reason (e.g., the candidate has a potential exposure, is symptomatic, is being tested, or has a positive test result). If the PTR is making the decision	Unlikely to be resolved at the time of the dual offer.	Y

Code	Refusal Reason	Description	Workgroup Notes	Carry Over?
		to refuse offers due to the pandemic, please select 'Candidate refused' as the refusal reason for the offer		
726	Candidate temporarily ineligible due to insurance or financial issue	PTR is temporarily ineligible for transplant due to insurance or financial related reasons	Unlikely to be resolved at the time of the dual offer.	Υ
727	Candidate unavailable	PTR is unavailable (e.g. traveling) or could not be contacted	Candidate may now be available or contactable at the time of the dual offer.	N
728	Candidate refused	PTR refused the offered organ	Members noted that a candidate may be interested in a dual offer having previously refused the single, though it would be rare.	N
	Histocompatibility Related			
730	No candidate serum for crossmatching	No candidate serum is available for crossmatching	Members noted that for all histocompatibility related reasons, the refusal should be carried over a dual kidney offer is unlikely to change the refusal.	Y
731	No donor cells/specimen for crossmatching, or no time for crossmatch	No donor cells or specimen for crossmatching or no time to complete a crossmatch		Υ
732	Positive physical crossmatch	Physical crossmatch result between donor and PTR is positive		Υ
733	Positive virtual crossmatch/unacceptable antigens	Virtual crossmatch result between donor and PTR is positive or PTR has donor- specific antibodies that are considered contraindications to transplant		Υ

Code	Refusal Reason	Description	Workgroup Notes	Carry Over?
734	Number of HLA mismatches is unacceptable	Number of HLA mismatches between donor and PTR is unacceptable		Υ
	Disease Transmission Risk			
740	PHS risk criteria or social history	PHS risk criteria for donor or other reasons related to social history. If a candidate refuses the offer for PHS risk criteria, please select 'Candidate refused' as the refusal reason for the offer.	Members noted that disease transmission risk would not decrease in a dual offer, such that all disease transmission risk codes should be carried over.	Y
741	Positive infectious disease screening test: CMV, HBV, HCV, etc.	CMV, HBV, HCV, HIV, HTLV, VDRL, etc. donor testing is positive		Y
742	Donor infection or positive culture	Donor has an active infection or positive culture results (e.g. meningitis)		Y
743	Malignancy or suspected malignancy	A malignancy or potential malignancy is suspected with the organ		Υ
744	Epidemic/Pandemic – Donor	Donor related epidemic/pandemic reason. This may include reasons such as donors with high exposure risk, no testing available, positive or indeterminate test results, or if a different specimen type is preferred		Υ
	Donor Specific			•
750	Donor medical history, specify*	Donor medical history is not clinically suitable for PTR		N
751	Donor instability/high vasopressor usage	Donor has prolonged hemodynamic instability and/or requires high vasopressor use		N
752	Prolonged downtime/CPR	Donor has experienced prolonged downtime and/or CPR		N
753	DCD donor neurological function/not expected to arrest	DCD donor has high neurological function and is not expected to arrest in time		N

Code	Refusal Reason	Description	Workgroup Notes	Carry Over?
754	VCA graft appearance or quality, specify **	VCA graft is unsuitable due to appearance or quality reasons such as incompatible skin tone, tattoos, scars, bruising, ecchymosis, hematoma, etc.		N/A
	Logistics		T	
760	Resource time constraint (OPO, TXC, donor hospital, etc.)	Time constraint for transplant imposed by the OPO, TXC, donor hospital, etc.	Members noted that due to the specific logistics considerations involved in dual kidney, these codes are not appropriate to carry over.	N
761	Donor family time constraint	Time constraint imposed by the donor family		N
762	Recovery team availability	Recovery team or local recovery team is unavailable to perform procedure (heavy workload, etc.)		N
763	Transplant team or transplant facility availability	Transplant team is unavailable to perform transplant procedure (heavy workload, etc.)		N
764	Transportation availability	Transportation for the organ cannot be obtained		N
765	Exceeded policy defined response time (OPO only)	Response was not received from the center within the time period specified in policy		N
	Other	T		,
790	Disaster Emergency Management Consideration	Use only in the event of a natural disaster, regional emergency, etc. that is affecting the operations or recovery of organs	Issue may be resolved by time of dual kidney match	N
798	Other, specify*	Use only when the reason does not fit the other refusal reasons available. Provide a detailed description of the reason the organ is being refused.	Members noted that due to variability in how this code is used, it should not be carried over.	N

<sup>\*</sup>When this field is selected, a text box will appear requiring members to further specify refusal reason

<sup>\*\*</sup>When this field is selected as a refusal reason, a text box will appear *allowing* members the option to further specify the refusal reason

A member asked for a program whose refusal was carried over, if the organ procurement organization (OPO) would be able to undo the refusal if the program is interested in the dual offer for their candidate. Staff answered that this depends on how the Workgroup envisions this functioning. One option would be to have the candidate screened completely off in the case of a carried over refusal, such that they do not appear on the dual kidney match run at all. Another option would be to create a new bypass code, so that the candidates still appear on the dual kidney match run but are bypassed. A member commented that from an OPO perspective, a cleaner match run would be ideal, however, there should be a pathway for if the transplant program input the wrong refusal code or wants to be on the match run for the dual offer after declining for a qualifying reason. Staff noted that this would be doable and some options can be presented to the Workgroup at a later date. A member asked if it would be easier to have the candidates bypassed from an efficiency metrics standpoint. Staff noted that program acceptance metrics are not based on bypasses or filters. A member stated that a cleaner match run would benefit OPO staff greatly.

#### Next Steps:

The carry over refusals worksheet will be sent back out to Workgroup members for further review and comment. The Workgroup will continue to work through carry over refusals on their next meeting. Once finalized, the Workgroup recommendations will be reviewed by the OPTN Kidney Transplantation Committee.

#### **Upcoming Meeting**

April 24, 2023

### Attendance

- Workgroup Members
  - o Renee Morgan
  - o Jason Rolls
  - o Jillian Wojtowicz
- HRSA Staff
  - o Jim Bowman
- Other Attendees
  - o Gretchen Lazic
- UNOS Staff
  - o Kayla Temple
  - o Kieran Mcmahon
  - o Thomas Dolan
  - o Lauren Motley
  - o Ben Wolford
  - o Carly Layman