OPTN Kidney & Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
October 11, 2022
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney & Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo teleconference on 10/11/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Exceptions, Attributes, and Clinical Guidance
3. Closing Remarks

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

1. Welcome and Announcements

The Chair welcomed the Workgroup to the meeting. Staff then provided a brief refresher on the purpose of the Workgroup. The Workgroup will:

- Establish a framework for review boards for kidney and pancreas and identify exceptions that can be requested in continuous distribution
- Develop and provide recommendations to the OPTN Kidney Transplantation Committee and the OPTN Pancreas Transplantation Committee for their approval to be incorporated into the August 2023 continuous distribution proposal.

Staff reviewed the timeline for the Workgroup. January 2023 is the target date for recommendations to be sent to the relevant committees.

2. Exceptions, Attributes, and Clinical Guidance

Staff provided a refresher on prior Workgroup discussions and then presented on identified possible exception requests.

Calculated Panel Reactive Antibody (CPRA)

Presentation summary:

Staff explained CPRA as a possible exception, including the rating scale. The new Board-approved CPRA calculator is inclusive of all loci and most alleles, which should prevent most issues. However, an exception pathway could correct for new discoveries about sensitization that the calculator does not account for.

Summary of Discussion:

A member described a concern that CPRA should not be a possible exception request, because it is a calculated value and not a subjective one. This member stated it would be unjust to apply an exception to one candidate because of a flaw in the calculator without applying that to every candidate. The Chair agreed and stated that they could not think of any scenario where an exception would make sense from a sensitization standpoint. A member explained that an example of a possible exception could be when

a patient has a higher CPRA rating from past testing, but now has a value that is less favorable. The Chair explained that would be difficult to justify, but that the Workgroup would take it under consideration and get more information from the OPTN Kidney Committee and the OPTN Histocompatibility Committee. The Workgroup agreed that these thoughts about CPRA as an exception request would also apply to kidney-pancreas and pancreas patients.

Blood Type

Presentation Summary:

For blood type, staff explained the kidney rating scale which is based on donor blood type and maintains current screening. It uses a points-based scale to distinguish between compatible blood types and gives points relative to the access to donors each blood type has. For pancreas, the rating scale is binary, awarding 100 points to identical blood types and 0 points to compatible blood types.

Staff described a possible example of an exception request for blood type from a case several years ago: an A2B patient with a high anti-A1 IgG titer, where the program is only comfortable accepting an A2B organ for this patient. This may be a case where the patient's access is more limited than is reflected in the rating scale.

Summary of Discussion:

Staff asked if the presented example would be an appropriate exception request. Members explained that this type of testing is atypical for an AB patient in their experience. Staff explained that if this example does not make sense or reflect the reality of transplant candidates, it may point to not having blood type as a type of exception request. A member stated that in their view, this is similar to CPRA because blood type is a calculated value and not a matter of subjectivity.

A member asked for clarification on which blood types are prioritized by donor blood type in the current allocation scheme, then explained that a possible exception could be if a center wants to expand access to different blood types for a hard to match patient outside of the typical allocation scheme. Staff explained that this was the goal with having separate attributes for blood type and CPRA. For example, in the case of a 100 percent CPRA blood type B candidate, they will receive points for both to accurately reflect a lower level of access.

After this discussion, the Workgroup agreed that blood type should not be a possible exception request.

Prior living donor

Presentation Summary:

Staff explained prior living donor as an attribute and described that a kidney candidate will be classified as a prior living donor if any organ was donated, the donation occurred in the US or its territories, and the candidate's physician reports the name and hospital of the recipient and the date of donation.

Summary of Discussion:

Staff asked if this should be considered for a possible exception request. The Chair explained that priority might make sense depending on the organ donated, because someone donating a liver has a higher chance of being sicker than a Vascular Composite Allograft (VCA) donor. Staff explained that the OPTN Living Donor Committee stated that living donation of any organ should be considered for the priority, to honor the intent of donation regardless of the clinical pathway by which the prior donor is now listed for transplant.

A member described a possible exception request being someone who donated as a living donor outside the US. Several members agreed that the spirit of living donation should be honored, no matter where

or when the donation occurred. Staff cautioned that this may be outside the scope of an exception request, however, that the Workgroup would be able to put this down as a tentative yes and then make sure that an appropriate pathway exists to verify and give priority for donation outside the country in line with OPTN policy. The Workgroup agreed that prior living donor priority should apply to kidney, kidney-pancreas, and pancreas alone.

Pediatrics

Presentation Summary:

Staff explained the pediatric rating scale as binary based on their age at time of registration, but that possible exception requests may be patients who were listed shortly after their 18th birthday due to some unforeseen circumstance by the hospital, such as a natural disaster, that prevented earlier listing.

Summary of Discussion:

Staff asked if this should be considered as a possible exception. A member described that they would be in favor of this to account for candidates who are not listed until after their 18th birthday. This member suggested that if a candidate began dialysis before age 18, they should be eligible for the pediatric attribute, regardless of whether they were listed or not. Another member agreed and stated that this could account for late referral if a candidate could show that their estimated glomerular filtration rate (eGFR) level was under 20 before age 18.

A member described concerns about implementation and scope, explaining that giving the pediatric point retrospectively may shift allocation to candidates with lower compliance. A member explained that in their view, candidates should be given the benefit of the pediatric points if to no fault of their own, they were delayed in referral or listing. The Chair explained that both sides of this are valid concerns. A member stated that the experience of having a 17-year-old candidate who is medically sick enough to be listed but cannot because of social or financial concerns is common, and that some centers will list these patients regardless of the concerns to gain the pediatric point to benefit the candidate.

The Workgroup agreed to consider the pediatric attribute for kidney, kidney-pancreas, and pancreas alone as an exception request, but requested more guidance and information.

Kidney-after-liver safety net

Presentation Summary:

Staff explained OPTN Policy *8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*. To qualify as a as a prior liver recipient, a candidate must have received a liver transplant, but not both a liver and kidney from the same donor. The kidney-after-liver classification gives priority if both:

- The candidate is registered for a kidney before the one-year anniversary of the liver transplant
- The date of registration is at least 60 days but not more than 365 days after the liver transplant, and at least one of the following is met:
    - GFR or measured or estimated CrCl less than or equal to 20 mL/min
    - The candidate is on dialysis

Staff explained that a possible exception request could arise if a candidate needs the priority either earlier than the 60 days or slightly beyond the 365 days, due to administrative lapse or another reason.

Summary of Discussion:

Staff asked if this should be considered as an exception request. Several members agreed that this sounded reasonable. A member described a concern that this exception request may not promote

programs taking responsibility for checking kidney labs of patients. A member described that this is a reasonable exception, but that the guidelines would need to be extremely strict to prevent programs from using the exception request to express frustration with the kidney-after-liver policy. This member advocated for an exception only in the case of administrative issues and not patients on the cusp, clinically speaking, of getting priority.

Members described kidney primary non-function after heart and kidney transplant as a case where a patient may need the priority before 60 days and expressed confusion of if the patient would qualify for the safety net in this case. A member described a concern that qualifying after a dual transplant might disincentivize the use of the safety net and that in their view, centers should need to choose between dual transplant or safety net.

The Workgroup felt comfortable moving forward with kidney-after-liver safety net as a potential exception request.

Proximity Efficiency

Summary of Discussion:

Members agreed that because proximity efficiency is calculated at the time of the match run, it is not eligible as a potential exception request. There was no further discussion.

3. Closing Remarks

Staff thanked Workgroup members for their attendance and stated that the remaining attributes will be considered in their next meeting.

Upcoming Meeting

- October 25, 2022

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Bea Concepcion
  - Dean Kim
  - Elliot Grodstein
  - Todd Pesavento
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - None
- **UNOS Staff**
  - Alex Carmack
  - Jennifer Musick
  - Joann White
  - Keighly Bradbrook
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Kieran McMahon
  - Thomas Dolan
  - Kayla Temple