OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
March 28, 2023
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney and Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo Teleconference on 03/28/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution
3. Recap: Review Board Process
4. Discussion: Second Appeal Review Body

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

1. Welcome and Announcements

The Chair welcomed the Workgroup members to the call.

2. Check-in: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution

Staff gave a brief overview of the Workgroup's decisions to date on kidney and pancreas review boards in continuous distribution.

Presentation summary:

OPTN heart, liver, and lung review boards quickly review specific, urgent-status patient registrations for candidates on the respective waiting lists. Review board members review and submit individual votes to collectively determine whether these listings are appropriate, based on the clinical information provided and the OPTN policies and guidance. Specific to continuous distribution, review boards allow members to submit an exception request when they think their candidate is not well-represented by the general allocation policies, significantly enhance the flexibility of organ allocation policy, and allow the OPTN and Committees to collect information that can provide insight into where policy modifications may be appropriate.

For now, large volumes of exceptions are not expected for kidney and pancreas review boards immediately post-implementation of continuous distribution, due to small patient populations in these particular attributes and the fact that policy does not currently utilize multi-factorial medical urgency scores for kidney and pancreas. The limited impact to current populations means that it may be necessary and appropriate to start small and potentially modify the structure of the review board in future iterations. Having a review board in place will allow for more flexible implementation and policy development in the future.

Summary of discussion:

There was no discussion.

3. Recap: Review Board Process

Staff gave a recap of the review board workflow.

Presentation summary:

A transplant program submits an attribute-based exception for their candidate, including the justification narrative supporting their request. The OPTN Contractor staff review the request, redact sensitive patient information, and submit it to the review board. Once submitted, the five calendar day clock begins. Seven reviewers are assigned to each case. If the reviewers do not vote within three days, they will be replaced by another reviewer at random. If they are not able to vote, participants may request that the case be reassigned to another randomly selected reviewer. Participants can also mark themselves out of office.

An exception case will close when a majority approval or denial is met, or the case reaches the end of the timeline of five days, whichever is first. The transplant program receives an email notification with the outcome of the case. In the event of a tie, the benefit will be given to the candidate and the exception will be approved.

If the exception request was denied, the transplant program has the option to submit an appeal within 14 days of the denial notification. Once submitted, the five day clock starts again on the case's lifespan. The first appeal is reviewed by the same participants that denied the initial request. The second appeal will go to a reviewing body.

During the review, participants have access to other attribute exception cases for that candidate where a decision has been made. Participants can also see all exception cases they have previously voted on and review redacted comments from other participants. The OPTN contractor can also assign and reassign cases.

Summary of discussion:

There was no discussion.

4. Discussion: Second Appeal Review Body

Staff went through specific decision points regarding the second appeal review body, and asked members to weigh in, continuing the discussion from last call.

Presentation Summary:

Pediatric Cases

For kidney, the appeal review team (ART) includes both adult kidney reviewers and pediatric kidney reviewers. Pediatric kidney reviewers are prioritized for pediatric cases, and vacancies will be filled with adult kidney reviewers. For pancreas, the ART includes both adult pancreas reviewers and pediatric pancreas reviewers. Pediatric kidney reviewers are prioritized for pediatric cases as much as possible, and vacancies will be filled with adult pancreas reviewers. It is more likely to have an insufficient number of pediatric pancreas reviewers. Pediatric pancreas reviewers are still able to review adult cases as well. Staff shared that according to the bylaws, in order for a program to be approved with a pediatric pancreas component, the pancreas transplant program must identify a qualified primary pediatric pancreatic surgeon and transplant physician. These primaries must meet the same requirements for general primary pancreas transplant surgeons and physicians. In order for a program to be approved with a pediatric kidney component, the program must identify a qualified primary pediatric kidney

transplant surgeon and transplant physician. There are additional requirements regarding clinical or fellowship pathways, surgery minimums, direct involvement requirements, and more.

In lung continuous distribution, lung pediatric reviewers are those from a program that have performed at least one transplant for a candidate under the age of 12 in the last five years and have an active pediatric lung component.

- Decision points: What qualifications should a pediatric pancreas reviewer have? How to define this? What qualifications should a pediatric kidney reviewer have? How to define this?

Transplant Program Representative

In the initial case, transplant programs may opt to have a representative join the call and present their candidate's case. This representative may give additional context about the candidate's situation and answer questions, and leaves before deliberation. However, the representative is not required to join in order for a case to be discussed and voted on.

- Decision point: Should a representative from the transplant program be permitted to join the ART call?

Timeline

The ART must meet and make a decision within 14 calendar days of receiving the appeal. If a decision is not made or a meeting is not held within the 14 days, the candidate is granted the appeal by default.

- Decision point: How long should the ART have to review and vote on the second appeal?

Summary of Discussion:

Pediatric Cases

The Chair asked if the lung requirements account for physicians moving around to new jobs, where their experience in the last few years may not correspond to their current institution. Staff explained that for lung, the requirements specify that the reviewer must be from an active pediatric lung program. A member stated that the requirements for lung do not transfer well to pediatric pancreas transplant because of the rarity of the procedure. This member noted that so few doctors have experience in performing pediatric pancreatic transplants.

The Chair suggested that a requirement for pediatric pancreatic reviewers could be that they have performed at least one pediatric pancreas transplant in the past five years. A member agreed. One member suggested that pediatric hepatologists may be suitable reviewers. A member disagreed, stating that hepatologists would not have the appropriate expertise. Members discussed pediatric multi-visceral transplants. Staff noted that this review board would be for exceptions for the kidney-pancreas and pancreas-alone listings and would not include multi-visceral listings.

A member noted that it would be helpful to have a pediatrician as a part of the ART if adequate pancreas-specific members could not be found. Members reached an initial agreement to include pediatric nephrologists on the pancreas pediatric ART because of the rarity of physicians with the appropriate pancreatic pediatric experience. A member suggested having quotas to fill for members

with pancreatic experience, then filling the remaining spots with members that have pediatric experience, with a requirement that there is at least one pediatric reviewer on each pediatric pancreas case.

The initial definition of a pediatric pancreas reviewer is as follows:

- Has performed at least one transplant for or worked with at least one pediatric pancreas patient in the last five years
- Is from a center with an active pancreas component

Members then discussed adding that members can be a pediatric nephrologist to this list, or if stating that remaining members could be filled with members of the kidney pediatric ART would be sufficient. A member stated that it would be important to ensure the following three types of members on the pediatric pancreas ART: a pediatric nephrologist (with or without pancreas experience), a nephrologist with pancreas experience (with or without pediatric experience), and a transplant surgeon with pancreas experience. A member agreed with this suggestion.

Members then discussed the definition for a kidney pediatric ART member. The Chair suggested that members be from a program with an active pediatric kidney component, and have performed at least two transplants on a pediatric patient in the past three years. Members asked for data to confirm how many people this would encompass, and staff noted that they would have to double check. However, staff did note that there were around 1400 pediatric patients, so this would probably lead to an adequate number of reviewers. Members noted that both surgeons and nephrologists would qualify. One member noted that perspectives may be different depending on how many pediatric patients the reviewers have experience with and center volume differences. This member noted that figuring out how large the pool is may help in possibly tightening the criteria to ensure adequate pediatric experience of ART members. One member suggested adding an age cutoff to require that reviewers treated at least one patient under the age of twelve, for instance, to ensure experience with young pediatric patients. Staff noted that the Workgroup would need clinical justification for this age split, however, this could be asked about during public comment. Staff also noted that for lung, there was precedent for a clinically relevant age cutoff in the former scoring system, which was transferred to continuous distribution. The Chair noted that it would be important to include reviewers with experience transplanting younger patients, and a member asked if it would be possible to include a requirement for experience with pre- and post-adolescent pediatric patients. Staff noted that there is a requirement for a primary pediatric kidney transplant surgeon in the OPTN Bylaws, which states that at least three transplants must have been on a recipient less than six years old or less than 25 kilograms at time of transplant. Members added this to the list, specifying that one of the two transplants on a pediatric patient in the past three years must be from a patient under the age of six or weighing less than 25 kilograms at the time of transplant.

Transplant Program Representative

Members were in favor of permitting a representative to join the ART call. One member asked how this would work logistically, and staff noted that for liver, there are specific timeframes and there is an established procedure that this Workgroup could mirror. No members were opposed to this.

Timeline

A member stated that 14 days would be too long. Staff noted that medical urgency is a retrospective review. A member noted that seven days seems appropriate. Staff noted that the candidate only receives the exception status before review for kidney medical urgency, while all other exception statuses are only granted after a decision by the review board.

Next Steps:

The Workgroup will resume discussion on the next call.

Upcoming Meeting

- April 11, 2023

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Ajay Israni
  - Bea Concepcion
  - Maria Friday
  - Michael Marvin
  - Todd Pesavento
  - Steven Almond
- **UNOS Staff**
  - Carol Covington
  - Darby Harris
  - Joann White
  - Kaitlin Swanner
  - Jennifer Musick
  - Kayla Temple
  - Kieran McMahon
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan