

OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup

Meeting Summary

March 14, 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 03/14/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Check-in: 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 and staff 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 raise a flag 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:

A member stated that the graphics in the presentation were helpful.

4. Discussion: Second Appeal Review Body

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

Presentation Summary:

Membership

Potential membership on the appeal review team (ART) is considered a responsibility of the review board. Members would commit for 1-2 years.

- Decision point: How long should members be committed to the appeal review team?

Chair

The ART is chaired by an active member of the OPTN Kidney or Pancreas Transplantation Committees. In the event that an appropriate and willing Chair could not be found, the Chair could be a clinical member of another OPTN Committee. The Chair is assigned to all second appeal cases and may review these cases with the ART. The Chair only votes in the case of a tie as a tiebreaker or in order to ensure a minimum number of votes.

- Decision point: Do you support having the Chair vote only as a tie breaker?

Pediatric Cases

For kidney, the 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.

- 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?

Summary of Discussion:

Membership

A member asked if the dates that people roll off the ART can be staggered such that the ART isn't left with experience gaps. The Chair agreed with this as a way to provide continuity to the ART. Staff noted that the ART will have a Chair that will add consistency and leadership. The Chair stated that a longer member commitment term would be preferable. Members discussed different member turnover options. Members reached initial consensus that, for the first iteration of the review board, half of the members serve for two years and half of the members serve for one year. After that, new members have a two-year commitment, ensuring that the membership refreshes by half every year. Members discussed refreshing the members every six months, but this may pose logistical barriers.

Chair

The Workgroup Chair agreed that the Chair of the ART should be an active Committee member. A member explained that it may not be practical, in some cases, to have another OPTN Committee member be the Chair of the ART. The Workgroup Chair stated that the ART Chair should be allowed to vote on all cases. Staff noted that having the Chair vote only in a tie would be a way to give the ART a way to break ties, something that the Workgroup was previously concerned about. The Workgroup Chair explained that the ART should use the ART Chair's expertise by having them as a voting member in all cases. A member agreed.

Workgroup members then discussed what to do in the event of a tie. There may be instances where an ART member is unable to make the call, creating an even number of votes that may result in a tie. A member explained that in the event of a tie at the highest level of appeal, the benefit should be given to the patient, and the exception should be approved. A member disagreed with this, explaining that a tie should not default to approve an exception. This member explained that the Chair could vote, and also serve as the tiebreaker vote if needed. The Chair and another member agreed with this. However, one member stated that the ART should advocate for the patient and approve the exception in the case of a tie.

A member asked if the ballot is public or secret. Staff noted that the members' votes are confidential. This member also explained that it is important to have the Chair vote on all cases.

Staff explained that the Chair would not be able to vote twice and noted that the Chair would be guiding the discussion and providing input, even if they are not always voting. A member asked about holding another vote in the case of a tie to try to reach a plurality. Staff noted that the review board system does not allow for a re-vote and noted that there may still be an issue if the fourth vote is still a tie. The

Chair noted that if a candidate's case has reached the third level of review and is still resulting in a tie, there is reason to approve the exception. Members discussed this, and reached an initial consensus to have the ART Chair be a voting member, and ties defaulting to an approval, via a Workgroup vote.

Pediatric Cases

Members were comfortable with the proposed set up for pediatric cases. The Chair asked if there were pancreas specialists that only manage pediatric patients. A member noted that this would be rare, because pediatric pancreas transplants are usually in combination with some other organ, or for teenagers. Pediatric pancreatic expertise is relatively rare.

Regarding which qualifications a pediatric pancreas specialist would need to have for participation on the review board, a member suggested that a kidney-pancreas surgeon who performs pediatric surgeries would be appropriately qualified. Members discussed difficulty in defining specific qualifications because of the rarity of pediatric pancreas transplants. Staff suggested that reviewers could self-identify as having experience in pediatric pancreatic transplant, and that the Workgroup could decide to keep the guidance for a pediatric pancreas reviewer looser. However, this may lead to people identifying as a pediatric reviewer who may not have appropriate expertise. The Chair suggested that a possible qualification could be having worked with at least one pediatric candidate in the past three years.

Staff noted that the Workgroup can continue this discussion next call, and that this would be something that could be asked about during public comment.

The meeting was adjourned.

Upcoming Meeting

- March 28, 2023

Attendance

- **Workgroup Members**
 - Asif Sharfuddin
 - Bea Concepcion
 - Ajay Israni
 - Namrata Jain
 - Reem Raafat
 - Todd Pesavento
- **UNOS Staff**
 - Austin Chapple
 - Carol Covington
 - Joann White
 - Keighly Bradbrook
 - Kieran McMahon
 - Kayla Temple
 - Lauren Mauk
 - Lauren Motley
 - Lindsay Larkin
 - Sarah Booker
 - Thomas Dolan