

OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup

Meeting Summary

April 25, 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 04/25/23 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

Staff and 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 and information about review boards in continuous distribution in general.

Presentation summary:

OPTN heart, liver, and lung review boards quickly review specific, urgent-status patient registrations for candidates on the respective waiting lists. These registrations are generally patients for whom the medical urgency algorithms and system does not appropriately represent, and for whom additional priority is appropriate. 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. This is meant to balance appropriate review and fairness to individual patients with fairness to all other patients, who are appropriately represented by the system. 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. Staff noted that this is not the final version of the review boards.

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. Votes are tallied utilizing Robert's Rules of Order definition of a majority as "simply more than half." 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.

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 meeting.

Presentation Summary:

Appeal Review Team (ART) Leadership

The Workgroup had previously decided that the appeal review team (ART) is chaired by an active member of the OPTN Kidney or Pancreas Transplantation Committees, and in the event that an appropriate and willing Chair cannot be found, the Chair could be a clinical member of another OPTN Committee. Also, the Chair is assigned to the cases and will review the cases with the ART members. The Chair is always a voting member, and ties default to an approval. A decision that the Workgroup still needs to finalize is what should happen if the Chair is unable to join the call. Previously, the Workgroup had recommended that a Vice Chair be expected to join the call, followed by Committee leadership, followed by a volunteer call leader.

Staff presented a recommendation for the Workgroup to consider: the Review Board includes a Vice Chair, who is also expected to join the ART call and would be able to lead the call in case the Chair cannot. The Vice Chair would also be assigned to each case and be expected to join each call. In the case that both the Chair and the Vice Chair could not attend, the call could be led by a member of the ART who is already present on the call. Staff noted that including Committee leadership in this process may present difficulties, considering that they may be less familiar with the review board process and may have limited availability.

Membership of the appeal review team (ART) would be members of the review board and the chair would be an active voting member. The Workgroup discussed definitions for pediatric reviewers, discussed case review occurring in a meeting setting as opposed to over email, and decided that a transplant program representative should be permitted to join the ART call, but is not required to. A decision that the Workgroup still needs to discuss is surrounding the timeline of the second appeal case.

Minimum Number of Votes and Reviewers

The Workgroup had previously decided that the minimum number of reviewers for the first level of appeal would be two. For the second appeal, the staff recommendation is that the minimum number of reviewers is three. This ensures that there is peer review and avoids a tie where possible. It is also recommended to default to an approval if the minimum is not met and another call could not be convened. Staff asked members to weigh in on this recommendation.

Membership

Previously, the Workgroup agreed that the ART membership would be pulled from the Review Board pool and that potential membership on the ART is considered a responsibility of the Review Board. The Workgroup also agreed that members of the ART should be committed for two years, such that half of the body would be rolling off each year to ensure continuity. Staff asked members to weigh in on how many members should be on the ART. The recommendation would be 10, plus the Chair and Vice Chair, for a total number of 12.

Summary of Discussion:

ART Leadership

The Chair stated that the Staff recommendation made sense and seemed reasonable, and noted that including Committee leadership may lead to less consistency in review. Members agreed that this was reasonable and feasible.

Minimum Number of Votes and Reviewers

A member asked how the balance of clinical expertise would be decided (surgeons versus nephrologists). Another member stated that it may not be important to specify, because the assumption is that all reviewers would have a baseline amount of knowledge. The original member stated that in some cases, surgeons or nephrologists may be better suited to certain case types. Staff noted that the ART call is a conference call and members would be able to discuss the case live. The Chair noted that by second appeal, there should be plenty of previous information to help reviewers decide, and that it would be unlikely that reviewers would not be able to come to a decision.

A member stated that a minimum number of votes of three for the ART made sense. Members agreed that in the case that the minimum is not met, the case should default to an approval. The Chair noted that although objectivity and peer review is important, a lack of reviewer availability should not disadvantage or delay a candidate's case. Members were comfortable with a minimum number of reviewers of three.

Membership

The Chair asked how large the National Liver Review Board (NLRB) is, and staff responded that the general review board pool is comprised of upwards of hundreds, but for the ART the number is 18 reviewers (nine programs who submit a primary and an alternate). Staff noted that the members on the Kidney and Pancreas ART would be expected to attend and review all second appeal cases, and cautioned against making the number too small or too large. The Chair noted that the membership should be more than 12 but less than 18. Staff explained that the Workgroup had decided on the ART to meet twice monthly, however, that will not be included in the guidelines so could change if need be. The Chair asked how long the calls are, and staff noted that it depends on the case volume.

The Chair suggested having a membership of 15 but asked staff for possible downsides to having that number be higher. Staff explained that it can be more difficult to coordinate and review with a higher number, but that a higher number means a higher likelihood of having more members available at one time. The Chair stated that the number should be high enough to avoid ever reaching the minimum number.

The Chair asked how often NLRB members are unable to make the calls. Staff answered that it is rare to not have enough reviewers on because of having alternates. Staff noted that for Kidney and Pancreas review boards, the preference would be to avoid having primary and alternate reviewers because it has proved difficult to coordinate in some cases and may be less critical in continuous distribution because of the new system in which region is comparatively less important. The Chair also explained that membership of 12 could make sense, and the Workgroup reached agreement to have a membership number of 12.

Next Steps:

The Workgroup will resume discussion and begin finalization of these recommendations on the next call.

Upcoming Meeting

- May 9, 2023

Attendance

- **Workgroup Members**
 - Asif Sharfuddin
 - Ajay Israni
 - Beatrice Concepcion
 - Dean Kim
 - Michael Marvin
 - Reem Raafat
- **HRSA Representatives**
 - Jim Bowman
- **UNOS Staff**
 - Kaitlin Swanner
 - Jennifer Musick
 - Kayla Temple
 - Kieran McMahon
 - Krissy Laurie
 - Lauren Motley
 - Lindsay Larkin
 - Ross Walton
 - Thomas Dolan