OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
April 11, 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 04/11/23 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 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:

A member asked how programs and reviewers would be notified. Staff clarified that both are notifications by email, and the member commented that an email may be easy to overlook. Staff noted that a text option is being explored for feasibility, but that this would not be included in the operational guidelines that the Workgroup is currently building. This member asked about reviewer pool size, and staff noted that the Workgroup would return to that question in a future meeting.

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:

The Workgroup had previously decided that membership of the appeal review team (ART) would be members of the review board, that the chair would be an active voting member, discussed definitions for pediatric reviewers, discussed case review occurring in a meeting setting as opposed to over email, and 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.

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? Considerations include:
    - Timeliness and fairness to the candidate and program
    - Meeting cadence
    - Feasibility of scheduling and logistics

Meeting Cadence

- The ART will meet through regularly scheduled conference calls
    - If there are no cases to review, the call will be cancelled
    - If the group is not meeting frequently enough, scheduling may move to ad-hoc
- Call frequency and scheduling will not be specified in the operational guidelines, in order to allow for increased flexibility
- Based on a 14-day case timeline, the ART would need to meet every two weeks

Chair

The ART is chaired by an active member of the Kidney or Pancreas Committees. In the event an appropriate and willing chair cannot 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.

- Decision point: what if the Chair is unable to join the call?
    - Recommended: the ART call moves forward without the Chair
    - The Chair would be expected to join the call, but is not required to be present to move the case forward
    - Timeliness and fairness to the patient are factors, as well as the potential for a conflict of interest that would prevent the Chair from joining

<u>Summary of Discussion:</u>

Timeline

A member asked for clarification on what happens if a meeting cannot be held for the ART. Staff explained that in this case, the prior decision making was that the candidate is granted the appeal by default, because they should not be penalized for an issue with the system. The member stated that if a case has been denied twice already, it is interesting to consider that the candidate may get their case approved by default. This member stated that 14 days seemed reasonable, however. The Chair stated that the concern of approving by default may be mitigated by having a shorter case timeline, and added that there may be candidates with medical issues who need a timely decision. However, the timeline needs to be long enough to avoid having issues with convening the ART. The Chair asked how long the meetings for the ART may be, to get a sense of volunteer commitment. Staff answered that for liver, they have an hour long, weekly call and typically review around six cases per hour.

A member asked about a general sense of how many cases are approved from the first review in the liver review board. Staff answered that they do not know the exact proportions. The Chair stated that knowing the relative expected workload would be helpful. Staff answered that for liver, there were many appeals at first, but as the ART evolved, there are fewer cases. A member asked how many times a

second appeal decision changes upon third appeal. Staff noted that they do not have exact numbers, but because the ART is led by a chair and permits a representative from the transplant hospital to present the case, it is possible that there may be a different case outcome with the additional deliberation permitted by a second appeal. Also, all reviewers that previously voted to deny a case need to provide rationale, so it is possible that the transplant program could respond to the information in the rationale upon second appeal.

A member stated that the Workgroup should consider professional relationships and emotions into the review board process, because of their experience with other review-board type transplant processes. This member stated that alliance to a program may impact decisions. Staff noted that the presenter is anonymous to the ART, and that reviewers use alternate names on the calls. Also, voting is captured separately from the call to reduce the likelihood of someone voting to approve or deny based on other ART members' decisions.

The Chair asked if a 14-day timeline sounds appropriate to members, noting that more than 14 days seemed too long, but that the ART may struggle with a shorter timeline. A member agreed. Staff noted that this would be an upper limit, and if the ART needed to meet more frequently, that would be permitted.

Meeting Cadence

Staff asked for input on meeting cadence. A member stated that it would be preferable to have a standing call, because schedules do fill up. This member suggested a weekly call such that the 14 day deadline would not ever become an issue. A member stated that weekly would be okay, knowing that they may almost always be cancelled if there are low case volumes expected. Staff noted that the liver pediatric review team is in a similar situation and has experienced success with a weekly standing call that is often cancelled.

Chair

A member asked if it would be possible to assign a Vice-Chair. Staff answered yes, but that there would still be the possibility of both the Chair and Vice-Chair being unable to join. A member remarked that they would need someone to lead the call, and a possibility would be to have the ART vote at the beginning of the meeting for someone to lead the call. Staff noted that one option could be that the OPTN Kidney Transplantation Committee's Chair, Vice-Chair, or ex-officio could join the call and lead it in this rare instance. The Workgroup Chair remarked that this seemed like a viable option, and the first choice would be the active OPTN Kidney or Pancreas Transplantation Committee Chairs if both the ART Chair and Vice Chair are unable to join. A member stated that this would put the OPTN Kidney or Pancreas Transplantation Committee Chairs on the spot, and asked if the substitute Chair would be a voting member of the ART. A member stated that tagging in the OPTN Kidney or Pancreas Transplantation Committee Chairs or Vice-Chairs makes sense because they would be well-versed in the policies themselves.

A member asked if there are separate review boards for kidney and pancreas, and staff confirmed that yes, there would be two review boards and two ARTs. This member stated that they supported having both an ART Chair and Vice Chair, and having the Committee Chair and Vice Chair as back-ups if the ART leadership was unable to join. Several members agreed with this suggestion.

Staff asked if the ART Vice Chair would attend all calls as an expectation, or if they are only going to be a substitute for the Chair. The Workgroup Chair explained that in their view, the Vice Chair would not be expected to join each call as they would be a backup option. A member asked what would happen if the Chair has a last-minute emergency that prevents them from joining the call. This would mean very short

notice for the Vice Chair. This member explained that in their view, both the Chair and the Vice Chair would need to be present at each call. A member suggested that in the rare occasion that the Chair could not attend, the call could just be rescheduled. The Chair noted that it would be potentially logistically complicated to try to align two people's schedules instead of just one.

"Staff noted that both the Chair and ART members would be expected to understand and be up to date with OPTN Policies and Guidance." Also, the members would have the chance to review the case ahead of time. Staff noted that it may be possible to have the call move forward without the Chair present. A member asked if staff is also present on the call, and staff noted that they will be on the calls. This member noted that knowledge of policy only goes so far, because the appeal requestor will likely be outside the policy criteria anyway, especially if it has reached second appeal. Staff noted that the review board is meant to be a peer review by clinical experts.

A member asked why the review board would need a Chair at all, if all members will have clinical expertise and knowledge of OPTN Policy. Staff noted that having a Chair can be helpful for being a liaison for the Committee and spotting trends in second appeal cases that may point to a need for policy changes. The Chair also would lead discussion and guide the call. This member noted that these were good points, and stated that it would be important to have the Chair for running the meeting. The Workgroup Chair noted that while all members would give input on the call, the Chair is important in guiding the discussion.

The Workgroup Chair asked if the Workgroup needed to decide what would happen if the Review Board Chair and Vice Chair and the OPTN Kidney or Pancreas Transplantation Committee Chair and Vice Chair were all unable to make the call, and staff answered that yes, the Workgroup needed to decide this. The Chair suggested that in this case, the review board could proceed with deciding the case without a leader. A member suggested that if there is a quorum on that call, the remaining members could nominate a one-time Chair to lead the call. The Workgroup reached an initial consensus that if the Review Board Chair and Vice Chair and the OPTN Kidney or Pancreas Transplantation Committee Chair and Vice Chair were all unable to make the call, the remaining members could agree on a one-time discussion facilitator to lead the call, so that the case can move forward.

Next Steps:

The Workgroup will resume discussion on the next call.

Upcoming Meeting

- April 25, 2023

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Ajay Israni
  - Dean Kim
  - Reem Raafat
  - Stephen Almond
  - Todd Pesavento
- **UNOS Staff**
  - Joann White
  - Kaitlin Swanner
  - Jennifer Musick
  - Kayla Temple
  - Lauren Motley
  - Ross Walton
  - Thomas Dolan