

OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup

Meeting Summary

February 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 02/14/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: Review Board Case Flow
3. Discussion: Case Appeals and Appeal Review

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

1. Welcome and Announcements

The Chair welcomed the Workgroup members to the call.

2. Recap: Review Board Case Flow

Staff gave a brief recap of the Workgroup's decisions to date on review board case flow.

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:

The Chair asked about providing text reminders, and staff answered that this idea is up for potential future incorporation.

3. Discussion: Case Appeals and Appeal Review

Staff reviewed the process of submitting an appeal request and possible outcomes, then asked members to weigh in on the outstanding decision points.

Presentation summary:

Staff asked who should review the case upon a second appeal. Some options include Committee leadership, a subset of the Committee forming an appeal review team, or the entire Committee to review the second appeal. Staff noted that the National Liver Review Board (NLRB) includes an appeal review team of nine reviewers who meet regularly to review the submitted appeals. If quorum is not met, the appeal goes to benefit to the patient. Staff noted some of the pros and cons to each approach.

Summary of discussion:

The Chair asked if a representative from the program joins the review board calls, and staff answered that in the current Liver appeal review team, a candidate or center representative is typically present on the calls. Members were opposed to having Committee leadership alone review the cases, because they would like to ensure more than two people are reviewing and voting.

A member asked what the meeting format would look like, and staff answered that currently, the National Liver Review Board (NLRB) uses standing conference calls for the appeal review team (ART). The reviewer terms and other review board conditions are outlined in the NLRB operational guidelines.

The Chair asked for clarification on what Committee-level review entails, and staff answered that most often, the Committee level review is delegated to a Subcommittee to ensure timeliness.

A member suggested that a Subcommittee of the larger Kidney and Pancreas Committees would be best suited to review second appeals because of their regular meeting schedule and knowledge of policies and procedures. A member asked how to account for pediatric cases. Staff noted that kidney and pancreas may be in a unique position for ensuring adequate pediatric experience, depending on which framework the Workgroup decides on, because Committee members may not have specific pediatric experience.

One member stated that in their experience, the NLRB members are well-informed due to the case volume and that the program is well-represented throughout the process. Staff noted how center-specific conflicts of interest would be handled by excusing particular participants.

The Workgroup was comfortable moving forward with Subcommittees of the Kidney and Pancreas Committees to review second appeals, noting that the Subcommittee may need to pull reviewers from the review board pool to review pediatric cases. The Chair suggested that the Subcommittee term should be the same as the term that the members serve on the larger Committee. For the reviewers that may serve on the Subcommittee who are not on the larger Committee, the Chair suggested that they serve one-year terms.

The Workgroup discussed the pros and cons of various sizes of the Subcommittee. A member suggested a seven-person team with a quorum of four would be sufficient for the Subcommittee. The Chair suggested a larger pool size may be better for ensuring adequate review. Staff noted that the NLRB has a review team lead or Chair to help guide conversation.

The Chair noted that a combination of the current Liver and Lung second appeal protocols may be best for Kidney-Pancreas.

Upcoming Meeting

- February 28, 2023

Attendance

- **Workgroup Members**
 - Asif Sharfuddin
 - Antonio Di Carlo
 - Ajay Israni
 - Bea Concepcion
 - Dean Kim
 - Maria Friday
 - Michael Marvin
 - Reem Raafat
 - Todd Pesavento
- **UNOS Staff**
 - Austin Chapple
 - Darby Harris
 - James Alcorn
 - Jennifer Musick
 - Kayla Temple
 - Joann White
 - Keighly Bradbrook
 - Kieran McMahon
 - Lauren Mauk
 - Lindsay Larkin
 - Sarah Booker
 - Thomas Dolan