OPTN Kidney Medical Urgency Workgroup
Meeting Summary
April 25, 2023
Conference Call
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Jim Kim, MD, Co-Chair

Introduction

The Kidney Medical Urgency Workgroup (the Workgroup) met via Citrix GoTo Teleconference on 04/25/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Introduction: Workgroup Task and Development of Kidney Medical Urgency
3. Consideration of Medically Urgent in the Transition to Continuous Distribution
4. Discussion: Development of Guidance for Use by the Kidney Review Board

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

1. Welcome and Announcements

The Co-Chairs welcomed the Workgroup members to the call and briefly introduced the task of the Workgroup.

2. Introduction: Workgroup Task and Development of Kidney Medical Urgency

The Workgroup's task was presented, as well as some background information about how medical urgency was developed originally.

Presentation summary:

The Workgroup will review the history of kidney medical urgency and its definition as currently in policy, determine how to update the definition for inclusion in the continuous distribution proposal, and begin developing guidance for the eventual kidney review board regarding kidney medical urgency cases.

The *Addressing Medically Urgent Candidates in New Kidney Allocation Policy* was approved by the OPTN Board of Directors in 2020 and implemented on March 15, 2021. In prior policy of donation service areas (DSAs), patients that were considered medically urgent were treated as exceptions to allocation policy and were transplanted out of sequence with physician judgement and agreement. When the current circles policy was implemented, the medically urgent classification was created within the kidney allocation tables.

Under the current definition, programs list their candidates as medically urgent in the OPTN Computer System and they receive the associated priority. Programs are required to submit associated documentation to support the medically urgent status. The Kidney Medical Urgency Review Subcommittee then retrospectively reviews the use of the medically urgent classification of candidates.

OPTN Policy 8.4.A.i states that the definition of medically urgent is as follows:

To qualify for medically urgent status the candidate must be:

1. An active candidate

2. Accruing waiting time, according to Policy 8.4: Waiting Time and

3. Certified by a transplant nephrologist and transplant surgeon as medically urgent, based on meeting the following criteria:

First, the candidate must have exhausted, or has a contraindication to, all dialysis access via all of the following methods:

- *Vascular access in the upper left extremity*
- *Vascular access in the upper right extremity*
- *Vascular access in the lower left extremity*
- *Vascular access in the lower right extremity*
- *Peritoneal access in the abdomen*

After exhaustion or contraindication to all dialysis via the methods listed above, the candidate must also either have exhausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the following methods:

- *Transhepatic IVC Catheter*
- *Translumbar IVC Catheter*
- *Other method of dialysis (must specify)*

Summary of discussion:

A member added that development of a definition of medically urgent in policy was an attempt to standardize wide-ranging regional definitions, and noted that the definition may need to be further refined.

3. Consideration of Medically Urgent in the Transition to Continuous Distribution

Staff gave some background information about expected functions in continuous distribution, and asked members to weigh in on how they see medical urgency fitting in.

Presentation summary:

In continuous distribution, programs whose candidates are not well accounted for by their composite allocation score (CAS) will be able to submit attribute-based exceptions to be considered by the Kidney Review Board. Medical urgency is one of the attributes that will be considered by the review board for CAS modifications.

The Workgroup was asked to consider if the current definition is appropriate for transition to a review board system. Staff noted that the current definition is somewhat up for interpretation: "contraindication" has been interpreted a variety of ways, there is significant variation in the clinical statuses of candidates listed as medically urgent, and there is a question of how to account for candidates who do not have access to more specialized forms of dialysis, such as transhepatic or translumbar.

Moving to continuous distribution, this Workgroup may wish to make the medically urgent definition more black and white. A stricter definition may reduce confusion and variation among medically urgent candidates. Programs whose candidate does not meet a potentially stricter definition would be able to petition the Kidney Review Board to look at the case further and decide if the candidate should be given that status.

In continuous distribution, all organs will have a review board. The OPTN Kidney and Pancreas Review Board Workgroup has been developing recommendations for the creation of a review board framework specific to kidney and pancreas. This Review Boards Workgroup recommended retrospective review of medically urgent candidates under the current definition, however, upon review of this definition in transitioning to continuous distribution, this Workgroup may elect to recommend prospective review of medically urgent candidates. Staff reviewed briefly how the review board is expected to function logistically, and noted that some of the operational considerations are still being discussed by the Review Boards Workgroup.

The Workgroup was asked to consider if it is appropriate to keep the definition of medically urgent the same for inclusion in continuous distribution, or if it would be appropriate to modify the definition to mean complete loss of dialysis, where imminent loss of dialysis or other, more complex situations could be handled by the review board. Staff noted that a goal that the Workgroup may have is to modify the definition such that it is very specific, so that if a candidate meets the definition, they would automatically qualify for medically urgent status, and everything outside of that specific definition would be subject to review board review.

Summary of discussion:

A Co-Chair asked what happens under current policy if a candidate or center does not have access to transhepatic or translumbar dialysis. Staff noted that historically, this has been interpreted as a contraindication, and the candidate would still be able to be listed as medically urgent. Centers are expected to attest to how this would be considered a contraindication as part of the documentation that is reviewed by the Subcommittee. The Co-Chair asked if there is a definition of "adjoining area" that programs would have to try to have their candidates have access to specialized forms of dialysis at, and staff answered that currently, there is not. A member answered that under current policy, it somewhat functions as an honor system subject to retrospective review. A member asked if there would be a downside to eliminating specialized access forms and only going with limb access points for the definition. Staff noted that this is one of the options the Workgroup could consider.

A member asked if every medical urgency case would be reviewed by the review board, or if certain cases would be automatically approved, such as how liver has a set of standard exceptions. Staff noted that the Workgroup may consider changing policy such that candidates clearly fit in to the definition, and then for those candidates who do not, the review board would review those cases, rather than making a set of standard exceptions.

A member noted that the goal of this would be to make the system as clean as possible and not have every case go to the review board. A Co-Chair noted that when the current definition was initially implemented, there was a lot of confusion, however, as time went on, programs seemed to understand the policy and the intent behind it a bit better. This Co-Chair noted that there may be different grades to medical urgency, such as someone who currently has no dialysis at all versus someone on their last access but who is able to be dialyzed.

A member asked how long it takes candidates to receive a transplant after they are listed as medically urgent, and staff answered that the median time to transplant for medically urgent cases is currently 63 days. A member stated that this timeframe would not be workable for a candidate with no access to dialysis. Another member added that prior to this standardized definition, Region One had a very strict definition, and in the rare case that a candidate lost all dialysis access, they received ample priority and were able to be transplanted in time. This member added that the question the Workgroup is being asked to consider is if they would like to keep the definition broad, or move to have the definition narrowed. A Co-Chair noted that one issue with a stricter definition would be patients who experience

delayed graft function who may need dialysis after transplant. A Co-Chair added that if the definition is modified to be stricter, those patients would need to go to the top of the list. This Co-Chair summarized some of the professional discourse they had heard about medically urgent candidates, explaining that a big change in the definition may be hard for centers to adopt along with continuous distribution. A member agreed.

Another member asked how much weight will be given to the medical urgency attribute in continuous distribution, and staff answered that in the scenarios submitted for additional modeling, the weight ranged around 15 percent, and that more information will be available once the results are back. A Co-Chair asked if it would make sense to have different classifications within the medically urgent status to account for patients with varying levels of urgency and if comorbidities could be factored into the definition. Staff noted that a change in the rating scale could be considered for a future iteration of continuous distribution, and would need to be a data-driven reason for any differentiation.

A Co-Chair noted that it may make more sense to leave the definition as is for transition to continuous distribution. A member agreed, and explained that these cases are complicated and it may present challenges to change this considered all the changes that are upcoming with continuous distribution.

Staff asked members if they were in favor of having all medical urgency cases be reviewed by the review board if they are not updating the definition. A Co-Chair explained that in their mind, some clear-cut cases should be "auto-approved" or be only reviewed by one reviewer and may not require full review, but that cases that involve contraindications or more complicated situations would warrant full review. A member suggested that if programs do not provide adequate reasoning as to why a patient has a contraindication, then those cases should be reviewed by the review board. Staff noted that one way to achieve the "auto-approval" goal would to be to modify the definition, such that cases who meet the definition do not get sent to the review board. A Co-Chair stated that they were in favor of modifying the definition to make it clear which cases will be sent to the review board, but not to change the spirit of the policy. Several members agreed that one case that should be approved may look like a candidate who has exhausted all limb and peritoneal access and be currently dialyzed by a transhepatic, translumbar, or other method of dialysis. A member stated this would make sense to be an auto-approval.

4. Discussion: Development of Guidance for Use by the Kidney Review Board

Staff explained that this Workgroup would have the opportunity to develop guidance for use by the kidney review board, and members discussed what this may look like.

Presentation summary:

In review of past medical urgency cases, the Medical Urgency Review Subcommittee could not make a decision in the majority of cases about whether the program listed a candidate as medically urgent appropriately, due to inadequate or irrelevant documentation and a lack of details on the candidate's clinical situation. The Subcommittee then created a document outlining recommendations for the kind of documentation programs should submit, including a brief and original narrative explaining access history (not an entire patient chart, labs, or progress notes), documentation that show that all potential access points have been exhausted or that the patient has a contraindication, with a history of each access point, and information about if the patient is currently dialyzed, where, and how. While these clarifications as to what kind of documentation programs should be submitting helped in review, there is room for additional clarification and guidance to be developed for use by the Review Board in deciding medically urgent statuses.

The National Liver Review Board has guidance documents for both programs and review board members to use, which outline the types of information programs should send and outline guidance for specific clinical diagnoses to aid review board members.

If the Workgroup elects to recommend to the Committee to narrow the definition of medical urgency, the future state may look something like the following:

- Candidates who meet the more stringent definition of medical urgency are listed as such and are eligible for the additional CAS points. Medically urgent cases will be monitored through routine monitoring reports and possible separate additional monitoring.
- Candidates who do not meet the more stringent definition but whose program thinks they should qualify for additional points submit a case with documentation to the Kidney Review Board. Medical urgency cases are reviewed retrospectively, so while the case is being adjudicated, the candidate receives the additional points. The Review Board meets and decides on their case, and the program may appeal if the case is denied.
- The Medical Urgency Review Subcommittee is dissolved, as its original function is replaced by the new Kidney Review Board.

Summary of discussion:

A member stated that the Workgroup would need to consider what should happen to candidates who may not have specialized forms of dialysis available to them and to candidates who, on the other hand, have ready access to specialized dialysis. A Co-Chair asked if there could be a geographical component added into policy, such that a program would be required to seek specialized dialysis for their candidate within a certain geographical radius. Staff reminded members that the role of the review board is to be a peer review of specialty cases that do not fit within policy, and noted that any policy would have to be considered from a compliance perspective.

A Co-Chair asked how the review board members would be expected to decide an outcome in the case, and a member and staff explained that guidance and the formatting of the system will make it clear to programs which type of information they should be submitting to the review board.

A member asked how many patients had been transplanted at medically urgent status, and noted that it seems like once the policy was in effect, programs began to learn who would be considered medically urgent and who would not qualify. Staff noted that the majority of cases that were listed as medically urgent and reviewed by the Subcommittee were added very soon after the policy was implemented but has since reduced.

Next Steps:

Staff will present more information and options based on this discussion for the Workgroup to consider at the next meeting.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Arpita Basu
  - Jim Kim
  - Asif Sharfuddin
  - Martha Pavlakis
  - Rachel Engen
  - Sanjeev Akkina
- **HRSA Staff**
  - Jim Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Jodi Smith
  - John Miller
- **UNOS Staff**
  - Ben Wolford
  - James Alcorn
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Kim Uccellini
  - Krissy Laurie
  - Ross Walton
  - Lindsay Larkin