OPTN Kidney Medical Urgency Workgroup
Meeting Summary
May 26, 2023
Conference Call
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Introduction

The Kidney Medical Urgency Workgroup (the Workgroup) met via Citrix GoTo Teleconference on 5/26/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Introduction: Workgroup Task and Development of Kidney Medical Urgency
3. Kidney Medical Urgency: Usage Data
4. Consideration of Medically Urgent in the Transition to Continuous Distribution
5. 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

A Co-Chair 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:

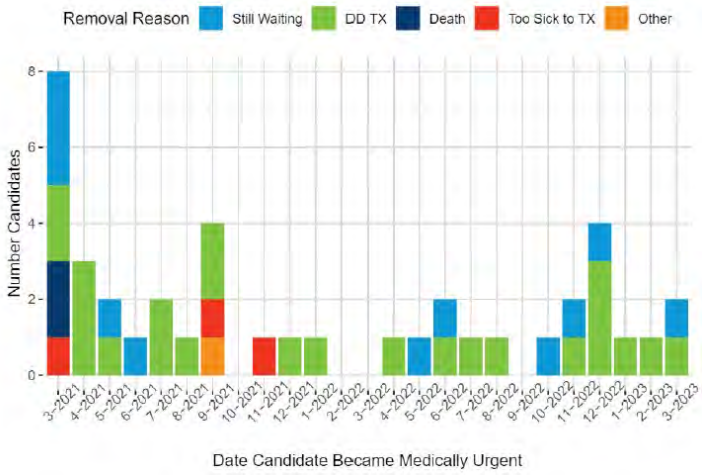
There were no questions or comments.

3. Kidney Medical Urgency: Usage Data

Some data about usage of the kidney medical urgency status was presented to members.

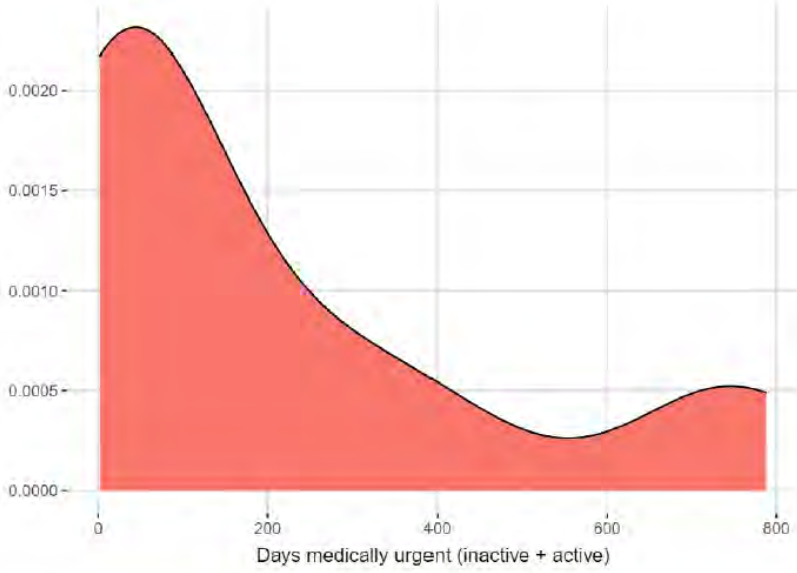
Data Summary:

Figure 1: Medically Urgent Candidate Cases from March 2021-March 2023



Since March 15, 2021, there have been 41 medically urgent candidates. Of those 41, 24 have been transplanted and 2 have died while waiting. Staff noted a bolus effect from when the policy was first implemented.

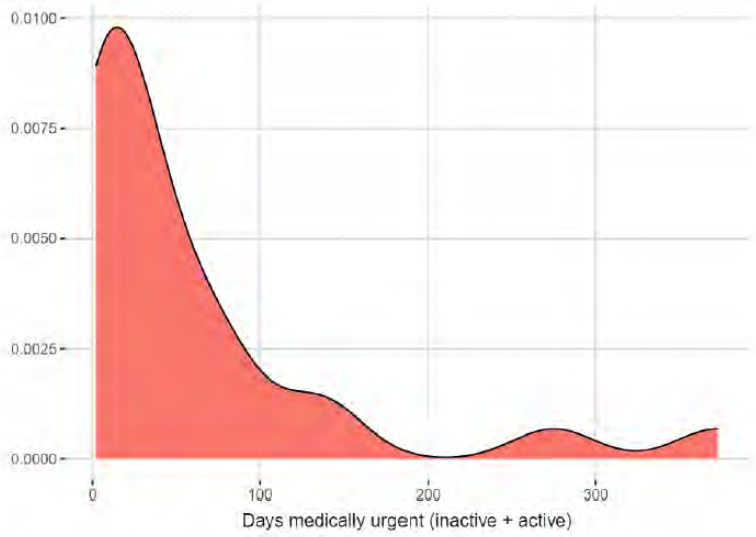
Figure 2: Time Waiting for Medically Urgent Candidates from March 2021-March 2023



The median time waited was 73 and the max was 788.

Staff noted that the majority of the candidates with the longest waiting times are highly sensitized.

Figure 3: Time Waiting For Those Medically Urgent Candidates Who Were Transplanted from March 2021-March 2023



Among those transplanted, the median time waited was 27 and the max was 373.

Some information about how medical urgency information is collected in the OPTN Computer System was explained. Programs can indicate if the candidate has exhausted dialysis access, is currently being dialyzed, or has a contraindication to dialysis via one of the following methods: transhepatic inferior vena cava (IVC) catheter, translumbar IVC catheter, or other, specify. Then, programs can specify whether the candidate has exhausted access, has a contraindication, or is currently being dialyzed by the method.

Programs selected “transhepatic” for 11 out of the 41 candidates. Of those, 8 had a contraindication and 3 are currently being dialyzed. Programs selected “translumbar” for 10 out of the 41 candidates. Of

those, eight had a contraindication and three are currently being dialyzed. No candidates were reported to have exhausted these methods. A total of 14 candidates were reported by their program to have exhausted, had a contraindication to, or currently on transhepatic or translumbar. This is because programs are allowed to select both, and they are not mutually exclusive. Programs responded "yes" to "other method" for the remaining 27 candidates and then specified in a free text field. Because of the small data population, further analysis of the free text field is not possible.

The data included six pediatric candidates, three of whom had a calculated panel reactive antibody (CPRA) of 99 percent and higher. Three are still waiting, and three have been transplanted.

Summary of discussion:

A member asked if any programs withdrew medically urgent status for their candidate during this period, and staff commented that anecdotally, one candidate did seem to have gone from medically urgent to not medically urgent. A member asked about the CPRA of these candidates. Staff answered that of the candidates who waited over a year, the majority had a CPRA of over 99 percent.

A Co-Chair stated that the policy and the intent of the policy seems to be being followed by programs due to the relatively low number of medically urgent candidates. A member agreed. Another member added that it is encouraging to see that a large proportion of the candidates are being transplanted very quickly.

4. 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.

In continuous distribution, all organs will have a review board. The task of the review boards is to adjudicate cases for candidates who fall outside policy but whose situation may warrant additional priority. 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.

The Workgroup was asked to consider which types of cases should not require review by the review board, and which types of cases should always be reviewed by the review board. Some specific examples were presented:

- Total loss of dialysis
- Candidate currently dialyzed by transhepatic, translumbar, or other
- Candidate has clinical contraindication to dialysis in one or more of the four limbs plus peritoneal access with exhaustion of other access points

- Candidate has situational "contraindication" to dialysis via transhepatic, translumbar, or other (such as center unable to perform)
- Imminent loss of dialysis (last access point that is failing)
- Saving one side for transplant

The 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 following case timeline assumes a retrospective review as currently recommended by the Review Boards Workgroup:

1. Transplant program submits an exception on behalf of their candidate
2. Once a majority approval or denial is met *or* the case reaches 5 days, the transplant program is notified of the decision.
3. If the request was denied, the program has the option to submit an appeal within 5 days of the denial notification. Once submitted, the 5 day clock restarts and follows the same process as above.
4. If the program chooses not to appeal, they have 5 days to remove their candidate from medically urgent status
5. If the exception is denied again, the transplant hospital has the option to appeal for a second time within 5 days.
6. The second appeal goes to the Appeal Review Body, which has 14 days from assignment to review, meet, discuss, and vote.
7. If the final decision is a denial, the program has 5 days to remove their candidate from medically urgent status

The current Medical Urgency Review Subcommittee will be dissolved, as its function will be obsolete in the new system served by the review board.

Summary of discussion:

On the question of which types of cases should and should not require review by the review board, a Co-Chair stated that in keeping with the spirit of the current policy, total loss of dialysis and a candidate who is currently dialyzed by transhepatic, translumbar, or other method should not require review and should automatically receive the status. A member agreed and suggested finding a way for programs to further specify what contraindication their candidate has and that cases involving either clinical or situational contraindications should be reviewed by the review board. This member stated that from a pediatric standpoint, one reason for medically urgent status is needing a small kidney, but this may be mitigated by transitioning to continuous distribution.

Regarding imminent loss of dialysis, such as a last access point that is failing, a member asked how adult nephrologists define this, and a Co-Chair answered that one case would be a candidate who has a contraindication to transhepatic and translumbar, and whose last remaining dialysis access point is not obtaining sufficient clearance, the candidate is getting blood clots at the site, or the clinical team has tried several interventions on the site. A member stated that these types of cases should warrant review by the review board, and several members agreed. A member suggested further defining this. One member suggested that because most medically urgent candidates are receiving a transplant within 1-3 months, a timeline for imminent loss of dialysis could be 3-6 months to anticipated total loss of dialysis.

Members agreed that saving one side for transplant is not within the spirit of the policy as written and if submitted, should require review by the review board. A Co-Chair asked if there are any pediatric-specific considerations that should be discussed. A member with pediatric expertise answered that the list of situations seemed complete, and that if a new situation came up for a pediatric candidate, that would probably warrant review by the review board.

The Workgroup consensus was that the following situations would not require review by the review board:

- Total loss of dialysis
- Candidate currently dialyzed by transhepatic, translumbar, or other

Other situations, including those presented in the list above, would require review by the review board. A member asked if only Safety Net and medical urgency cases can be submitted to the review board. Staff answered that the Review Board Workgroup reviewed all attributes and determined that these two attributes are candidate specific and may warrant composite allocation score modifications in some cases. However, if a situation comes up that is not accounted for by policy that warrants some candidates to receive additional priority, the review board could look at these cases under medical urgency even if the situation does not directly relate to dialysis access.

On the question of if cases submitted by the review board should be reviewed retrospectively or prospectively, a Co-Chair explained that retrospective review makes sense noting the case volume and time to transplant. A member asked how removing a candidate from medically urgent status would work in the case of a denial. Staff explained that the program removes their candidate in the event of a denial, and if this is not done within five days, the program is notified that they may be in violation of OPTN policy. A member asked what happens if a candidate receives a transplant at medically urgent status that is later denied by the review board. Staff explained that there is transplant at an unapproved status and then transplant at a denied status, and these two situations are being discussed by the Review Boards Workgroup, which is determining guidelines for this. A Health Resources and Services Administration (HRSA) representative asked if other organ review boards function in this manner. Staff noted that there is some variation among organs about how their review boards work and what they do in the event of a transplant at an unapproved or denied status.

A member asked if a case submitted for "saving one side for transplant" should be reviewed prospectively. Staff noted that the Workgroup will need to decide that all medically urgent cases will be reviewed either retrospectively or prospectively, and they will not be able to split it up by case type due to how the system works. A Co-Chair noted that a case like this may be an anatomic issue, but even in retrospective review, the review board will be able to determine if any given case is within the spirit of the policy. They noted that the data indicates that usage of the status has been appropriate. The Workgroup moved forward with the recommendation to maintain retrospective review.

5. 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. Staff showed members this guidance.[1] Members were asked to consider what should be included in a guidance document to aid review board members in deciding medical urgency cases.

Summary of discussion:

Staff worked through the following situations and named some items that should be included for each after reviewing the current Kidney Medical Urgency Documentation Recommendations to programs about what they should submit.

Candidate has clinical contraindication to dialysis in one or more of the four limbs plus peritoneal access with exhaustion of other access points

A member suggested demonstrating an anatomic abnormality, gastroparesis, gastro perforation, clinical history resulting in an inadequate peritoneal domain, or a history of vascular thrombosis not related to dialysis could be included in the guidance. This member added that for children, clinical contraindications could include candidates with pulmonary issues who cannot tolerate peritoneal dialysis due to pressure on the diaphragm and children on dialysis who experience dangerous refractory hypertension. A member added that these complications describe failure to achieve adequate dialysis or complication of inadequate dialysis. This member stated that for this situation, a program should need to demonstrate why they feel that despite having adequate access to dialysis, the candidate requires medically urgent status.

Candidate has situational "contraindication" to dialysis via transhepatic, translumbar, or other (such as center unable to perform)

A Co-Chair stated that programs should submit a statement attesting to the situation that is preventing their candidate from receiving this type of dialysis, noting that it would be difficult to outline specifics because of distance and insurance variability. Another member suggested leaving the guidance somewhat vague, such as that a transplant program would have to demonstrate that the candidate does not have access to the procedure within a reasonable distance and explain why this is the case. This member noted that insurance coverage is an important consideration.

Imminent loss of dialysis (last access point that is failing)

A Co-Chair suggested that it may be useful to specify a re-submission of documentation at a certain interval, such as every three months, to ensure that the medically urgent category is being used appropriately. Staff noted that re-submission of documentation to prove medically urgent status is not currently in the continuous distribution cross-organ review board framework, however, that this can be further discussed to determine feasibility. A member explained that perhaps in the guidance provided to

[1] Guidance to Liver Transplant Programs and the National Liver Review Board for: Adult MELD Exception Review, updated January 5, 2023.

programs, it should be specified that programs should be checking to see if their candidates still need the medically urgent status at regular intervals, and the expectation is that a program would remove their candidate from the status if they no longer clinically need it.

A member explained that documentation for this scenario should include how the candidate is currently dialyzed and documented problems with that access point (recurrent thrombosis, replacement of a catheter, or failure to obtain adequate dialysis despite interventions). A HRSA representative added that multiple surgical revisions would be another indication of a failing access point.

Saving one side for transplant

A member stated that this would not be a proper use of the medically urgent status and explained that if a program submitted this type of case, the justification would need to be extremely strong and detailed. The current recommendations given to programs states that one access point or side cannot be saved for transplant. A member explained that if the consensus is that this is not an appropriate use of the policy, it should not be in the guidance because it may encourage programs to submit exception requests for this situation. A Co-Chair agreed with this, noting that including it would open it up as possible use and suggested instead that if a program feels that their candidate in this situation warrants additional priority, it could be submitted in the "other, specify" category.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Arpita Basu
  - Jim Kim
  - Asif Sharfuddin
  - 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