OPTN Kidney Medical Urgency Workgroup
Meeting Summary
August 14, 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 8/14/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Introduction: Workgroup Task and Recap of Past Decisions
3. Recap Usage Data and "Other, Specify"
4. Data Collection Checklist
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 and staff welcomed the Workgroup members to the call and briefly re-introduced the task of the Workgroup.

2. Introduction: Workgroup Task and Recap of Past Decisions

The Workgroup's task was presented and an overview of the Workgroup's prior decisions on kidney medical urgency was given.

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 Workgroup will also recommend changes to the medical urgency data collection in the OPTN computer systems.

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)*

The Workgroup had previously decided the following:

1. The only cases that would not require review by the review board are total loss of dialysis (representing a true emergency situation) and candidate currently dialyzed by transhepatic, translumbar, or other method (noting that these are typically "last-resort" dialysis options).
2. Other candidate situations would require review by the review board.
3. Guidance will be specified as to what programs should be submitting and what reviewers should be considering as a part of the review process.
4. All review by the review board will be retrospective, allowing candidates to be granted the status while their case is under review. This will serve to not disadvantage any candidate who may be experiencing a medically urgent situation while their case is under review.

Staff presented a clarifying question to the Workgroup in regards to the prior decision to allow a candidate *currently dialyzed* by transhepatic, translumbar, or other method to qualify for medically urgent status without an exception request. Current policy also allows candidates to qualify for medically urgent status via *exhaustion* of one of the following methods: transhepatic, translumbar, or other method. The Workgroup was asked if they would like to keep this feature in the updated definition medically urgent status.

Summary of discussion:

Regarding the question of if the Workgroup would like to keep exhaustion of one of the following (transhepatic, translumbar, or other method) as able to qualify for medically urgent status without an exception request, a member stated that because these methods are rare and often a candidate's last option, exhaustion of one of the methods should be enough to qualify for the status without an exception request. A Co-Chair agreed. No members voiced opposition to this.

A member stated that from a pediatric standpoint, the current definition may seem to prevent candidates from access to transplant. Staff noted that the goal of this Workgroup is to determine how to transition the definition of medical urgency to a continuous distribution framework with a review board, and to appropriately account for all candidate situations, whether that be through policy or through review by the review board. A member stated that pediatric candidates may not fit into the policy definition, but that would just mean that they would need to submit a case to the pediatric-specific review board, and that this would appropriately accommodate the pediatric patients.

3. Recap Usage Data and "Other, Specify"

Some data about usage of the kidney medical urgency status was recapped to members and members were asked to consider the "other, specify" field.

Data Summary:

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.

Staff showed the submissions for the free text field, which ranged from responses you'd expect to see specified elsewhere on the form (such as peritoneal dialysis and access via a limb) to other, more rare types of dialysis (such as indwelling groin line, chest catheters, and Hemodialysis Reliable Outflow (HeRO) grafts).

Presentation summary:

Staff asked the Workgroup to consider the utility of the free text field and if it should be kept in the new framework for medical urgency. One option would be to eliminate the free text field, and if a candidate has a situation that is not accounted for via the new form, their program would just have to submit an exception request to the review board.

Summary of discussion:

A member stated that it is unclear why most of the answers were submitted in the free text field, as they do not appear consistent with the current definition in many cases. This member suggested eliminating the free text field and requiring programs to submit exception requests if their candidate did not meet policy requirements would be a good idea. A member agreed, noting that with the free text field, there is a possibility for some candidates to be getting an undue advantage.

The Workgroup reached consensus to remove the other, specify field and have programs that would have entered something into that field submit an exception request instead.

4. Data Collection Checklist

Staff ran through a data collection checklist with members to ensure that the new data collection is feasible.

Presentation summary:

Staff presented a checklist with rationale for each of the data elements, running trough intent, units of measurement, acceptable responses, non-plausible values, interpretability, availability, and burden of collection. The data elements as currently collected in the OPTN computer system will be updated to match the new recommended definition from the Workgroup for inclusion in the continuous distribution framework. While some buttons and options are changing, the process for programs submitting medically urgent cases will remain largely the same.

A new narrative, open-ended field will be created in the review board system for programs to describe their candidate's situation and why they require an exception. A place to submit documentation will also be included on this page.

Summary of discussion:

For the data element that requires programs to indicate that their candidate has exhausted dialysis access in all four limbs and via peritoneal access, staff asked if members would like to have this element as an assumption of the form (listed at the top), or a discrete element with checkboxes. A Co-Chair suggested having a yes/no option with system validation based on the response. A staff member from IT responded that it is important to balance the data burden with making sure programs are reading and understanding the data collection. Two members stated that programs may not read the element if it is just an assumption of the form. A Co-Chair suggested having at least one checkbox to ensure that programs were reading the element, but not one for each method. A Co-Chair recommended using the phrasing "all" instead of "each" and bolding and underlining "all" for clarity.

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

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

Staff explained the current recommendations for submission to the Medical Urgency Subcommittee as they are currently provided to programs. The Workgroup also needs to define the terms "exhaustion" and "contraindication" as they should be interpreted by both programs and reviewers. These definitions can be specified in the guidance documents and also in the forms themselves.

A crude, plain-language definition of each was presented to members as a starting point to then work off of:

Exhaustion: dialysis was tried at an access point and failed, and there is no indication that it will ever work again

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

Contraindication: a reason why dialysis cannot or should not be attempted at a site (noting that this can be for clinical and for situational reasons)

Members were asked to weigh in on this starting point and add details.

Summary of discussion:

A Co-Chair noted that an example of a contraindication would be intraabdominal adhesions for peritoneal dialysis and stated that a definition for exhaustion would be that a team attempted dialysis at a site, it failed, and there are no plans to try it again at that site because the clinicians know that dialysis cannot be achieved at that site again (it will fail). This Co-Chair noted that stenosis would be a good indication of exhaustion. The other Co-Chair explained that a better definition may be that a team attempted dialysis at a site, it failed, and there is no other viable vascular access available in that region.

A member noted that in the supporting documentation for a program submitting an exception request for a contraindication, a program should have to note the specific reason why dialysis is not going to be attempted at the site. As for the definition of contraindication, a Co-Chair noted that vascular patient characteristics, adhesions, too painful, and financial considerations would all be contraindications.

Staff asked if a candidate is missing a limb (such as an arm) and cannot attempt dialysis at that site, if that would represent exhaustion or a contraindication. A Co-Chair noted that if there is no viable vessel at that site after an attempt to achieve adequate dialysis, it would be considered exhaustion, however, if dialysis cannot even be attempted, it would be considered a contraindication. A member also explained that vascular anomalies and patient too small for vascular access would be considered contraindications. Another member added distal stenosis to the list.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Arpita Basu
  - Jim Kim
  - Steve Almond
  - Rachel Engen
- **HRSA Staff**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Ben Wolford
  - James Alcorn
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Kailin Swanner
  - Carlos Martinez
  - Lauren Motley
  - Rebecca Brookman
  - Rebecca Fitz Marino
  - Thomas Dolan