

**OPTN Kidney Transplantation Committee  
Kidney Medical Urgency Review Subcommittee  
Meeting Summary  
August 9, 2022  
Conference Call**

## **Introduction**

The Kidney Medical Urgency Review Subcommittee met via Citrix GoToMeeting teleconference on 08/09/2022 to discuss the following agenda items:

1. Review: Subcommittee Purpose and Goals
2. Closed Session: Confidential Medical Urgency Case Review
3. Review: Kidney Medical Urgency Definition and Background
4. Review: 1-Year Post-Implementation Monitoring of Kidney Medical Urgency Definition
5. Next Steps and Options

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

### **1. Review: Subcommittee Purpose and Goals**

The Subcommittee reviewed Policy 8.5.A.i *Medically Urgent* Status and the purpose and goals of the Medical Urgency Review Subcommittee.

#### Summary of discussion:

The Subcommittee had no questions or comments.

### **2. Review: Kidney Medical Urgency Definition and Background**

The Subcommittee reviewed the history of the kidney medical urgency definition and the documentation recommendations released by the Kidney Committee.

#### Presentation summary:

Documentation recommendations from the Subcommittee were released in a communication to all kidney programs in February 2022, to address incomplete/insufficient documentation submissions, which did not provide appropriate indication of candidates' medical urgency status.

- Communication recommended that programs provide a narrative summarizing and explaining access history, with attention to each access point
  - Be brief and original to describe the medical urgency of the patient
  - Documentation should list and explain all of the patient's accesses and failures, and reasons for contraindications to specific points
- All potential dialysis access points have been exhausted or contraindicated – one side or access cannot be saved for transplant
- If the patient is currently dialyzed, explain how and through which access point
- Programs are asked not to include approval of medically urgent status from other programs in their region or donor service area

The Kidney Medical Urgency definition was created to address medical urgency in circles based kidney allocation, and was developed rapidly in 2019.

- Previously, medical urgency definitions varied between donor service areas, with different criteria and practices
- During public comment, there was agreement that a candidate should have lost or have imminent loss of vascular access
  - Recognition that this is reflective of a small pool of people, which intentionally balances the strictness of the definition and level of priority given to those candidates
- Due to the low anticipated volume of cases, the Kidney Committee determined retrospective review was appropriate
  - Some concerns about gaming were revealed in public comment, with others emphasizing the importance of trust between transplant programs
  - Need to ensure medically urgent candidates are transplanted in a timely fashion
- Determination that contraindication should include cases where expertise required for translumbar and transhepatic accesses, or other dialysis accesses, is not available
  - Some programs and dialysis centers may not have the medical expertise necessary to place and utilize translumbar, transhepatic, and other advanced dialysis accesses
  - Pediatric patients may be contraindicated to certain accesses as a whole

#### Summary of discussion:

One member asked if programs fill out a specific form, or create an original document to be submitted when applying for medical urgency. The member asked whether the surgeon, medical director, or physician is required to create this document. Staff clarified that the program will compile their documentation when applying for medical urgency, and that this documentation needs to be signed off on by the transplant nephrologist and transplant surgeon. The programs will submit this case documentation in waitlist, as well as indicate whether each access point was exhausted or contraindicated, and how the candidate is currently dialyzed. The member noted that this seems like a lot of very specific information, and that it could be useful to create a form to standardize the documentation submitted and how these questions are answered. The member added that a guidance document of some kind could successfully do this.

### **3. Closed Session: Confidential Medical Urgency Case Review**

The Subcommittee had a closed session review of medically urgent kidney candidate cases. The Subcommittee found that documentation was more concise and appropriate after documentation recommendations were communicated to kidney transplant programs.

### **4. Review: 1-Year Post-Implementation Monitoring of Kidney Medical Urgency Definition**

Staff presented 1-year post-implementation monitoring data of the kidney medical urgency policy.

#### Data summary:

Since policy implementation on March 15, 2021, 29 candidates listed with a medically urgent status, of which 14 have been transplanted and 3 have died. The median time waited was 59 days, and maximum was 501. While candidates are able to keep the medically urgent status indefinitely, some candidates do become inactive and can change their status. For medically urgent candidates whose end status was the medically urgent status (status at transplant, status at removal, or current status), the median time waited was 87, and the maximum was 501. There was a bolus of new medically urgent cases following implementation of the policy, but this has since leveled out to about one new case per month.

### Summary of discussion:

One member noted that a little over half of patients listed at medically urgent were recent listings, while the others were listed in 2021. The member noted that it was reassuring to see that the medically urgent status is infrequently used, adding that it was never meant to be a large or increasing number of patients. The member remarked that the current rate of medically urgent cases seems appropriate. Another member agreed, and noted that the median time waiting also seems reasonable.

A member asked if programs must notify the OPTN in order to remove a candidate from medically urgent status, and staff explained that the program can remove a candidate from medically urgent status themselves. The member pointed out that some patients may be waiting longer due to being highly sensitized.

One member asked if previous reviews were correlated with this data, and staff shared that they were not, in order to protect patient-level data. A member asked if outcomes data could be pulled, given that medically urgent cases are typically intrinsically high risk. Staff shared that, when the definition of kidney medical urgency was first developed, the Kidney Committee reviewed data on outcomes for medically urgent candidates, and saw that those outcomes were typically worse, relative to non-medically urgent recipients.

A member asked if there were any incidents of a center submitting multiples of patients. Staff clarified that there have not been any incidents of a center submitting many of their patients as medically urgent, and that these cases are spread evenly amongst centers.

### **5. Next Steps and Options**

The Subcommittee discussed potential options regarding next steps.

#### Presentation summary:

The OPTN Kidney and Pancreas Review Boards Workgroup will be starting up this August, and will discuss kidney medical urgency. Kidney medical urgency will ultimately be included in the incoming Kidney Review Board, but until then, the OPTN Kidney Medical Urgency Review Subcommittee will continue to meet periodically.

The Kidney Medical Urgency Review Subcommittee discussed several options, if they determine some kind of action is necessary to clarify the policy:

- Develop a policy proposal updating policy language to clarify meaning of contraindication and potentially specify documentation requirements
  - Specifying this documentation could be considered data collection, and require Office of Management and Budget (OMB) approval
  - Updating this definition could be more controversial
- Develop a guideline or guidance document, similar to the National Liver Review Board
  - Could be incorporated into review boards, and operate as a review board guideline or guidance
- Determine immediate changes are not necessary and continue monitoring medically urgent cases while developing review boards.

### Summary of discussion:

One member remarked that, based on the data, the medically urgent status is being used appropriately, for the most part. The member noted that, though there have been some issues with the documentation provided, it may be best to tackle updates to medically urgent status requirements as

part of the development of the Kidney Review Board. Other members agreed. A member pointed out that the numbers are low, and that programs have, for the most part, aligned with policy.

The Subcommittee reached consensus to not pursue updates to the policy, nor the creation of a guidance document, in anticipation of the Kidney Review Board. Members agreed that meeting twice a year is an appropriate cadence for the Subcommittee.

#### **Upcoming Meetings**

- TBD

## Attendance

- **Subcommittee Members**
  - Martha Pavlakis
  - Jim Kim
  - Asif Sharfuddin
  - Bea Concepcion
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Ajay Israni
  - Grace Lyden
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Lindsay Larkin
  - Kayla Temple
  - Jennifer Musick
  - Ross Walton
  - Sara Moriarty
  - Stryker-Ann Vosteen