Addressing Medically Urgent Candidates in New Kidney Allocation Policy

OPTN Kidney Transplantation Committee

Background

- Current policy for medical urgency exceptions will be obsolete when Board-approved allocation policy is implemented
- There is not a consistently applied definition of medical urgency
- An estimated 100 candidates per year are considered “medically urgent” based on the various definitions used today

Proposal

- Standard definition for medical urgency
- New medically urgent classification for kidney allocation
- Documentation and oversight

Definition for Medical Urgency

First, the candidate has exhausted/contraindicated dialysis access via:

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

And the candidate is currently being dialyzed by or has exhausted/contraindicated dialysis access via:

- Transhepatic IVC Catheter
- Translumbar IVC Catheter
- Other (must specify)

Medically Urgent Classifications

Sequence A KDPI 0 – 20%	Sequence B KDPI 20 – 34%	Sequence C KDPI 35 – 85%	Sequence D KDPI 86 – 100%
100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Top 20% EPTS 0-ABDRmm (All) Inside Circle (All) National Pediatrics National (Top 20%) National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) National Pediatrics National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) National (All) Inside Circle (dual) National (dual)	100% Highly Sensitized Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ADBRmm Inside Circle Safety Net Inside Circle Inside Circle (dual) National National (dual)

Documentation and Oversight

- Transplant nephrologist and transplant surgeon approval required
- Medically urgent classification applied when data is entered in UNet^{SM}
- Documentation must be submitted to OPTN within 7 business days
- Review completed retrospectively by OPTN Kidney Transplantation Committee
- Cases that do not meet definition may be referred to MPSC for review

Feedback Requested

- Should any criteria be added to or removed from the definition of medical urgency?
- Do you agree with the proposed prioritization?
  - Should prioritization be limited to inside of the 250 NM circle?
  - How should these candidates be ranked relative to other classifications?
- What types of supporting documentation are appropriate for review?

Discussion

Extra slides

Current Policy

8.2 Exceptions

8.2.A Exceptions Due to Medical Urgency

Prior to receiving an organ offer from a deceased donor in the same DSA, a candidate's transplant physician may use medical judgment to transplant a candidate out of sequence due to medical urgency.

If there is more than one kidney transplant program in the DSA, then the candidate's physician must receive agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence and must maintain documentation of this agreement in the candidate's medical record.

Rationale

- Reviewed current available data to estimate the volume of medical urgency cases and review outcomes
  - Estimates likely no higher than 100 cases per year on the highest end of projections
- Reviewed international practices for medically urgent kidney candidates
- Reviewed policies and protocols from various OPOs
- Decisions based on sound medical judgement and clinical experience of committee members

International Practices

- Australia/New Zealand: offered the next compatible donor organ arising anywhere in these countries
  - Patients with a very high risk of death if they are not transplanted in near future (e.g. patients with renal failure who no longer have dialysis access)
- Eurotransplant: criteria for medical urgency listing, which adds 500 points for allocation, include:
  - Imminent lack of access for hemodialysis and/or peritoneal dialysis; Severe (uremic) polyneuropathy; Inability to cope with dialysis with high risk for suicide; Severe bladder problems such as hematuria or cystitis due to kidney graft failure
- UK: information available for priority listing for pediatrics
  - Potential imminent access or actual loss of dialysis access or when dialysis access is likely to become difficult within a short period of time; when special restrictions are required for suitable kidney, such as size, which significantly restrict donor access
- Canada: most regions have ability to list based on medical urgency, but availability of defined criteria, amount of consensus required, and priority given varies; survey reported rare use
  - Criteria available include uremic polyneuropathy, cardiomyopathy, and access failure

Policy and Protocol Summaries

Current Practices

- One Legacy
  - Two consultations from vascular surgeons confirming loss of vascular access
  - Consult stating that peritoneal dialysis cannot be performed
- Region 1
  - Emergency status should be limited to a life-threatening circumstance: life-threatening is restricted to inability to maintain access for dialysis. The emergency request is based upon the inability to dialyze because no further access is attainable. The policy infers that a leg graft access was either attempted or is contraindicated. Thus, all possible options for vascular and peritoneal access must have been attempted including the placement of a permcath. However, failure of catheter access alone is not a requisite determinant for emergency candidacy.
  - If there are two or more medical emergency candidates for a renal allograft only, the patient with the longest waiting time at the medical emergency status will receive the first available allograft.

Current Practices

- LifeSource
  - The candidate is seen at the transplant center requesting urgent status.
  - The listing transplant center obtains approval from each kidney transplant center director in the LifeSource DSA.
  - Prior to approving the medically urgent status listing, transplant centers have the option to request additional documentation or may request to examine the candidate (at the center's expense).The listing program is not obligated to fulfill the request.
  - A copy of the center-approval documentation is provided to LifeSource.
  - LifeSource reviews documentation for completeness and notifies the requesting center of the date the candidate's status is changed to medically urgent. Kidneys are allocated to the medically urgent candidate in accordance with policy.
  - If the candidate receives a kidney out of Match Result sequence (due to medically urgency status), LifeSource will provide appropriate documentation to the OPTN.

Current Practices

- Gift of Hope
  - Requesting center submits application and supporting documentation
  - Materials reviewed by the Gift of Hope Medical Director for sufficiency prior to circulation for vote by the 8 other renal transplant programs
  - Centers have 48 hours to vote for either approval or refusal for medical urgency status
  - Seven approval votes are required for priority status

Current Practices

- Donor Network West
  - Must be submitted in writing by the requesting physician or designee
  - Request must include supporting documentation and letter from nephrologist or surgeon
  - Request presented to a renal subcommittee for consideration
  - The Renal Subcommittee has the option to grant any request for medical urgency, to decline medical urgency but prioritize on the KDPI >85 list, or deny the request altogether, by a simple majority
  - If request is declined, it maybe appealed to the subcommittee with additional supporting documentation
  - If a candidate receives transplant due to medical urgency and is then re-listed due to Primary Non-Function, medical urgency status is restored

Current Practices

- NCNC DSA
  - Only a single medical urgency case in the last several years
  - The OPO receives a letter from the requesting center for the exception
  - The letter is shared with local centers in the DSA
  - Approval is received from all local centers
  - The OPO prioritizes the candidate and files all documentation in their variance tracking system

Current Practices

- Other Feedback Received
  - Some DSAs do not have documented practices for medical urgency, citing the rarity of such occasions
  - Some transplant programs manually get approval from all other transplant programs within the DSA without a procedural review

N (%) of Deceased Donors with an Accepted KI by whether any KI Candidates were Bypassed due to Medical Urgency of Another Candidate and whether an Accepting Candidate had a Medically Urgent Indication

	Kidney donors	Donors with a Kidney Accepted by a Medically Urgent Patient, as Defined by							
		WL Status='Critical' or 'Urgent'		Exhausted Vascular Access (TCR)		Exhausted Peritoneal Access (TCR)		Either Critical/Urgent WL or Exhausted Access on TCR	
		N	%	N	%	N	%	N	%
Any candidates bypassed due to medical urgency of another?									
No	32,147	77	0.2%	130	0.4%	206	0.6%	360	1.1%
Yes	57	33	57.9%	4	7.0%	3	5.3%	34	59.6%
All	32,204	110	0.3%	134	0.4%	209	0.6%	394	1.2%

OPOs bypassed candidates due to the medical urgency (refusal code 860) of another for 57 kidney donors, or about 10 per year.

N (%) of KI Registrations with Indication of Medical Urgency Status, as per Waitlist Status (5 or 6) or Exhausted Dialysis Access (TCR)

Kidney Registrations	Medically Urgent Patient, as Defined by							
	WL Status='Critical' or 'Urgent'		Exhausted Vascular Access (TCR)		Exhausted Peritoneal Access (TCR)		Either Critical/Urgent WL or Exhausted Access on TCR	
	N	%	N	%	N	%	N	%
109,797	53	0.0%	251	0.2%	239	0.2%	478	0.4%

478 kidney registrations on the waiting list December 31, 2014 had some indication of medical urgency.