

Title: Addressing Medically Urgent Candidates in New Kidney Allocation Policy **Sponsoring Committee:** Kidney Transplantation

What is current policy and why change it?

Currently, if a physician determines that a kidney candidate's condition is serious enough that they need a transplant immediately, they have the option to request approval from all other transplant hospitals in the same Donation Service Area (DSA) to give the candidate priority over others when a kidney is available. In December 2019, the OPTN Board of Directors approved a new kidney allocation policy that will replace DSAs with a 250 nautical mile circle around each donor hospital. This means that there will no longer be a standing set of transplant hospitals to approve requests for priority due to medical urgency. To make sure that this priority is used consistently, a defined practice to award this priority is necessary.

What's the proposal?

- Defines a medically urgent candidate
 - **Unable to receive dialysis** or at high risk for not being able to receive dialysis
- The candidate receives priority when a kidney is available within a 250 nautical mile circle

What's the anticipated impact of this change?

- What it's expected to do
 - Replace the existing medical urgency exception policy to align with the recently approved changes to kidney allocation policy
 - Help medically urgent kidney candidates get transplanted quickly
 - Ensure candidates receiving this priority meet a consistent definition of what is considered medically urgent
- What it won't do
 - \circ $\;$ Apply to every kidney candidate on the wait list

Themes to consider

- Qualifying medical urgency criteria
- Supporting evidence of criteria
- Appropriate priority over other candidates

Terms you need to know

- **Donation Service Area**: The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals
- **Donor hospital**: The hospital where the deceased or living donor is admitted
- Nautical mile: Equal to 1.15 miles and is directly related to latitude and longitude; used in aviation
- <u>Click here to search the OPTN glossary</u>

Public Comment Proposal

Addressing Medically Urgent Candidates in New Kidney Allocation Policy

OPTN Kidney Transplantation Committee

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OPTN

Addressing Medically Urgent Candidates in New Kidney Allocation Policy

Affected Policies:	8.2.A: Exceptions Due to Medical Urgency 8.5.C: Sorting Within Each Classification
	8.5.H: Allocation of Kidneys from Deceased Donors with KDPI
	Scores less than or equal to 20%
	8.5.1: Allocation of Kidneys from Deceased Donors with KDPI
	Scores greater than 20% but less than 35%
	8.5.J: Allocation of Kidneys from Deceased Donors with KDPI
	<i>Scores greater than or equal to 35% but less than or equal to 85%</i>
	8.5.K: Allocation of Kidneys from Deceased Donors with KDPI
	Scores Greater than 85%
Sponsoring Committee:	Kidney Transplantation
Public Comment Period:	January 22, 2020 – March 24, 2020

Executive Summary

Currently, prior to the OPTN Board of Directors' recent adoption of new kidney policies that remove DSA as a unit of allocation,¹ patients that are considered "medically urgent" are administered as exceptions to allocation policy. Specifically, policy allowed for exceptions for a candidate's transplant physician to use medical judgment to transplant a candidate out of sequence due to medical urgency."² Further, if there was more than one kidney transplant program in the same DSA, then the candidate's physician could seek agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence. These current policies will be obsolete when the newly-adopted allocation policy is implemented and DSAs cease to be a unit of allocation.

The OPTN Kidney Transplantation Committee (the Committee) is proposing the creation of a "Medically Urgent" classification within all kidney allocation tables. The purpose of this classification is to create priority for candidates who are at imminent risk of death due to an inability, or anticipated inability, to accept dialysis treatment for renal failure. The location of the proposed classification varies in priority across each of the four KDPI sequences in allocation. The classification grants medically urgent candidates increased priority within the 250 NM distribution circle only. Medical urgency would be defined as a candidate's inability to receive dialysis due to failure of dialysis access in both peritoneal and vascular methods. Additionally, leg graft access would have to be attempted, failed, or contraindicated for a specific reason. Finally, candidates would have to have lost or are imminently losing their last form of access, including transhepatic and translumbar inferior vena cava (IVC) catheters. These criteria were developed in order that the definition of medical urgency would include candidates with imminent loss of dialysis access and not exclusively candidates that have completely lost dialysis access.

¹ Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at https://optn.transplant.hrsa.gov/

² OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at https://optn.transplant.hrsa.gov/

A candidate's medical urgency would initially be indicated on their waitlist form under a new "Medically Urgent" status in the Waitlist data collection instrument. A candidate's status as "Medically Urgent" as defined in new policy would require members to submit supporting documentation to the OPTN. The OPTN Kidney Transplantation Committee would perform periodic retrospective review of the use of the new medical urgency classification via evaluation of supporting documentation. This evaluation serves to ensure member compliance with the proposed medical urgency policy.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding the following:

- 1. Do you believe any additional criteria should be added to or removed from the definition of "medical urgency" as proposed by the Committee?
- 2. Do you believe that the new medical urgency classification should receive priority outside of the 250 NM circle? Should medically urgent candidates outside of the circle receive priority before non-medically urgent candidates inside of the circle?
- 3. A new medical urgency classification has been included in each KDPI category for kidney allocation. The Committee requests feedback on the proposed prioritization within each sequence.
- 4. What types of supporting documentation do you believe are appropriate to ensure the medically urgent classification is being utilized as intended?

Purpose of the Proposal

When the Committee developed a proposal to remove DSA as a unit of allocation within kidney policies, its members recognized that a solution was necessary to ensure that medically urgent candidates received increased priority in allocation.³ Because medically urgency exceptions were previously granted at the DSA level of allocation, the Committee set forth to propose a way to address these critical candidates in a consistent fashion across the country.⁴

The Committee's proposal seeks to provide a rationally determined and consistently applied definition for medical urgency in order for candidates with imminent failure of access to dialysis can receive the appropriate priority in an expedient manner while still allowing for retrospective oversight.

Background

Prior to the OPTN Board of Directors' adoption of new kidney allocation policies,⁵ which removed DSA and region as units of distribution and implemented a 250 nautical mile (NM) fixed-distance circle; patients that were considered "medically urgent" were administered as exceptions to allocation policy. Specifically, Policy 8.2.A "Exceptions Due to Medical Urgency" stated that, "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."⁶ This language highlights the fact that there is currently no standard definition for what defines "Medical urgency" in current policy. Further, if there was more than one kidney transplant program in the same 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."

During the development of their proposal titled, "Eliminate the Use of DSAs and Regions in Kidney Allocation Policy,"⁷ the Committee recognized that it would need to address these medically critical candidates following the dissolution of DSA as a unit of distribution. The Committee developed an initial proposal and included that proposal within the Committee's greater geography proposal released for the OPTN Fall 2019 Public Comment Period.⁸

Following public comment, the Committee considered the feedback received concerning the medical urgency proposal and determined that further examination was necessary.

The Committee formed the Medical Urgency Subcommittee, which met several times to further develop an appropriate proposal and consider questions previously unaddressed in the initial proposal.

³ Meeting Summary for July 8, 2019 meeting, OPTN Kidney Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

⁴ Meeting Summary for August 19, 2019 meeting, OPTN Kidney Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

⁵ Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at https://optn.transplant.hrsa.gov/

⁶ OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at https://optn.transplant.hrsa.gov/

⁷ Elimination of DSA and Region from Kidney Allocation Policy, OPTN Kidney Transplantation Committee, August 2019, Available at https://optn.transplant.hrsa.gov/

⁸ Ibid.

Fall 2019 Proposal

At the time that the Committee developed their initial proposal for medical urgency, its members were proposing a 500 NM circle as the first unit in kidney allocation. The Committee decided that a proposal was necessary to ensure that medically urgent candidates retained priority in the new allocation system.⁹ The Committee briefly considered utilizing the 500 NM fixed-distance circle as the geographic boundary for medical urgency approval; however, the number of centers within a 500 NM circle could far outnumber the centers that exist within the current boundary (DSA), around which current policy was originally adopted.¹⁰ Furthermore, the center of that fixed boundary would change depending on the donor hospital, creating a system wherein a transplant hospital might have to receive consensus from a different set of programs than that of another transplant hospital only 50 NM away, for example.¹¹ The Committee also noted that these cases are seemingly rare, and the clinical criteria of what defines a medically urgent candidate may vary DSA-to-DSA in current policy.

The committee recognized the need for a consistently applied and rationally determined proposal and elected to treat these cases in a uniform manner across the country. The initially proposed kidney medical urgency policy would create a new "medically urgent" classification within kidney allocation tables. Transplant hospitals seeking to obtain the classification for one of their medically urgent patients would be prompted to apply for the status when certain clinical criteria are selected while initiating or updating the candidate's waitlist record. This form would have then received an expedited, prospective review by the Medically Urgent Status subcommittee. Subcommittee review was proposed to occur within four (4) calendar days. If the subcommittee approved the candidate for medically urgent status, the candidate would receive the classification. Future match runs would have reflected that classification for the candidate.

The Committee elected to vary the placement of the medically urgent classification based on the donor KDPI of the kidney being allocated.

The Committee considered the limited community feedback regarding the medical urgency component during its monthly meetings in August and September 2019.¹²¹³ In addition to considering this feedback, The Committee proactively contacted some OPOs and OPTN regional leadership in some regions that have their own processes and clinical definitions for medically urgent candidates under current policy.

Based on the limited feedback and the procedures received from voluntarily from transplant programs, the Committee concluded:

- 1. Medical urgency should be clinically defined and that definition should include the inability to receive dialysis as a result of failure of vascular access
- 2. The medically urgency classification priority should vary depending on the KDPI of the donor kidney

⁹ Meeting Summary for July 8, 2019 meeting, OPTN Kidney Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

¹⁰ OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at https://optn.transplant.hrsa.gov/ ¹¹ Ibid.

¹² Meeting Summary for August 19, 2019 meeting, OPTN Kidney Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

¹³ Meeting Summary for September 16, 2019 meeting, OPTN Kidney Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

- 3. Candidates' total allocation scores should be considered when prioritizing medically urgent candidates in the event that two appear on the same match run
- 4. The Committee should consider if multiple authorizations should be required in order to list a candidate as "medically urgent."

As a result of the limited feedback received as well as the desire to further consider the proposal before putting it forth for OPTN Board consideration, the Committee elected to remove the medical urgency component and its associated policy language from proposal titled, "Eliminate the Use of DSAs and Region from Kidney Allocation Policy." Instead, the Committee would convene a medical urgency subcommittee to continue developing the proposal as a separate policy project. This project received approval from the OPTN Policy Oversight Committee.¹⁴ This proposal represents the work of that medical urgency subcommittee and was approved by the greater Committee at their December 2019 meeting.¹⁵

Proposal

The Committee proposes the following to address medically urgent candidates in newly-adopted kidney allocation policies without DSA as a unit of allocation:

Definition

Currently, there is no standard definition in kidney allocation policy as to the characteristics of a "medically urgent" candidate. DSAs currently write their own definitions and define their own procedures for granting priority for these candidates outside of the match run. The Committee believes that by developing a standard, national definition based on current practice in the community, candidates across the country, regardless of whether their DSA had procedures for medical urgency priority before, will now have access via the proposed policy.

Medical urgency would only apply to registered candidates in active status on the kidney waiting list and would be defined by the following candidate characteristics:

- First, the candidate has exhausted (and/or has a contraindication to) all dialysis access via each 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
- Also, the candidate has exhausted dialysis access, is currently being dialyzed, or has a contraindication to dialysis via one the following methods
 - o Transhepatic IVC Catheter
 - Translumbar IVC Catheter
 - Other (must specify method)

¹⁴ Meeting Summary for November 14, 2019 meeting, OPTN Policy Oversight Committee. Available at https://optn.transplant.hrsa.gov/

¹⁵ Meeting Summary for December 16, 2019 meeting, OPTN Kidney Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

Medical Urgency Classification

The Committee proposes the creation of a new "Medically Urgent" classification to be placed in the kidney allocation tables within policy. The classification will receive different priority depending on the KDPI of the donor from which the kidney is being allocated. The priority of the new classification would be place in allocation tables accordingly:

- For Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, medically urgent candidates would be placed at Classification 7 after 100% cPRA 0-ABDR mismatch, 100% cPRA, local prior living donors, and local pediatrics
- For Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%, medically urgent candidates would be placed at Classification 7 after 100% cPRA 0-ABDR mismatch, 100% cPRA, local prior living donors, and local pediatrics.
- For Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%, medically urgent candidates would be placed at Classification 6 after 100% cPRA 0-ABDR mismatch, 100% cPRA, and prior living donors.
- For Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%, medically urgent candidates would be placed at Classification 5 after 100% cPRA 0-ABDR mismatch, and 100% cPRA.

The Committee proposes that, similar to current policy, priority for medically urgent candidates would only be awarded to medically urgent candidates inside the 250 NM initial allocation circle from the transplant program where the donor kidney is offered.

In the rare occurrence that two candidates with the medical urgency classification appear on the same match run, the Committee proposes prioritizing these candidates based on the number of consecutive days each candidate has been classified as medically urgent, with the tiebreaker going to the candidate with more days at status. Should both candidates have been classified as medically urgent on the same day, the candidates' total allocation scores will serve to prioritize the two candidates amongst one another, with the highest score receiving higher priority.

The Committee proposes that the medical urgency classification could be applied to Kidney-Pancreas (KP) candidates seeking an isolated kidney. However, the priority would apply only to the isolated kidney. The candidate could be classified as medically urgent to receive the isolated kidney, should that candidate meet the definition of medical urgency. Furthermore, the Committee proposes that if a medically urgent kidney-alone candidate transitions to a KP candidate that wishes to seek an isolated kidney, the medical urgency classification received for the initial kidney listing should automatically transition to the isolated kidney registration associated with the KP listing. No additional approval should be required.

The Committee also proposes that the medical urgency policy could apply to en bloc kidney offers if the candidate's program has opted-in to accepting these offers and the transplanting surgeon seeks to pursue this option for transplant.

Finally, the Committee proposes that if a medically urgent candidate has a classification with a greater priority than the new medically urgent classification, such as the classification for a candidate with "O-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible," then that candidate will

maintain the priority for the classification with the highest priority in allocation. No additional points or prioritization within that classification would be necessary.

Documentation and Oversight

The Committee proposes that the medical urgency classification should be applied to a candidate's listing only after new data fields on the waitlist data collection instrument are completed. These fields ensure that the candidate meets the clinical definition of medical urgency as proposed by the Committee. These fields would appear when a new "Medically Urgent" patient status on the waitlist form is selected. The fields require indication that the patient has exhausted or otherwise contraindicated all forms of access listed in the medical urgency definition. The candidate's transplant surgeon and transplant nephrologist must review and sign a written approval of the candidate's exhausted vascular and peritoneal dialysis access and the imminent loss of dialysis access via additional methods listed in policy. The transplant hospital must document this approval in the candidate's medical record and submit both documents to the OPTN within seven (7) business days of indicating status.

The Committee proposes that these data are retrospectively reviewed periodically by the OPTN Kidney Transplantation Committee. If during that review, the Committee believes that the medical urgency classification has been applied inappropriately and that further review is necessary, the Committee proposals referring oversight to the OPTN Membership and Professional Standards Committee (MPSC).

The following section outlines the subcommittee's deliberation and how the proposed policy was developed.

Subcommittee Deliberation

The Medical Urgency Subcommittee met 5 times throughout November and December 2019 to reconsider the original proposal, gather evidence, and develop a revised proposal for public comment feedback during the OPTN Spring 2020 Public Comment period. One of the guiding principles of the subcommittee's evidence-gathering process and deliberations was to try to mirror the current policy and practices of transplant programs within the new allocation environment. This would serve to reduce additional administrative burden or fiscal impact of the proposal and maintain the efficient placement of organs in accordance with the OPTN Final Rule while still maintaining a mechanism for medically urgent candidates to receive appropriate priority in allocation.¹⁶

Evidence Gathering

The subcommittee's primary focus concerning evidence gathering was to provide some context around the following questions:

- How often is the current medical urgency policy utilized?
- What are the current procedures utilized within DSAs to grant medical urgency?
- What patient outcomes can be expected for candidates that receive a transplant via medical urgency policy?

The subcommittee reviewed data between 2010 and 2014 regarding potentially medically urgent candidates and recipients. These candidates were defined as waiting in medically urgent or critical status

¹⁶ 42 C.F.R. § 121.8.

at time of listing or transplant, or had indicated on their transplant candidate registration (TCR) form that they had exhausted peritoneal or vascular dialysis access. The number of donors that were potentially allocated to medically urgent candidates was determined by examining the usage of bypass codes (refusal code 860) on kidney match runs due to medical urgency of another candidate.

The data showed that OPOs bypassed candidates due to the medical urgency of another for 57 kidney donors (approximately 10 donors per year, 0.2% of all deceased kidney donors). Looking at kidney registrations, there were 478 kidney registrations on the waiting list on December 31, 2014 that had some indication of medical urgency. Medical urgency was not concentrated to a specific geographic area. Post-transplant patient and graft survival were examined for kidney transplants potentially medically urgent as defined above. Potential medically urgent recipients received significantly lower KDPI kidneys and were more likely to be pediatric, be on dialysis at transplant, have HLA sensitization, and be a repeat kidney transplant. Recipients having some indication of medical urgency had significantly lower graft and patient survival within four years post-transplant, and were more likely to experience delayed graft function (defined as the need for dialysis within the first week post-transplant). The Committee also reviewed literature examining medical urgency practices around the globe. Among countries such as Australia, New Zealand, the United Kingdom, Canada, and the Eurotransplant system, most included some element of medical urgency in allocation, though exact criteria were not well defined.^{17,18} Generally, it included patients who had failed dialysis, is usually utilized through a consensus process, and impacts a small number of patients for organs available at a local level.

Similar to Committee deliberation of the original medical urgency proposal, The Committee proactively contacted each of the 58 OPOs to ascertain if there were any similarities in definitions and procedures concerning medical urgency under current policy. Several OPOs voluntarily shared their definitions and processes for consideration.

The subcommittee reviewed each of the voluntarily submitted process descriptions and definitions.¹⁹ Subcommittee members saw similar consistencies in terms of medical urgency definitions that were observed during evidence gathering during the OPTN Fall 2019 Public Comment period, specifically, that candidates qualify for medical urgency when they are unable to receive dialysis treatment due to the lack of vascular access.²⁰ Some differences were noted in the number of signatures were required at the candidate's transplant program before intra-DSA review was initiated.²¹

Definition Development

The subcommittee sought to develop a definition of medical urgency that would include candidates that were at "imminent risk" of losing access to dialysis as well as candidates whose dialysis access had been completely exhausted or otherwise contraindicated.²² In achieving this balance, the subcommittee

¹⁷ Sever and Goral. Kidney transplantation due to medical urgency: time for reconsideration? Nephrol Dial Transplant (2016) 31: 1376-77. Available at https://optn.transplant.hrsa.gov/

¹⁸ Prioritization for Kidney Transplantation due to Medical Urgency, Canadian Council for Donation and Transplantation, October 2006, Available at https://optn.transplant.hrsa.gov/

¹⁹ Meeting Summary for November 15, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

²⁰ Ibid.

²¹ Ibid.

²² Meeting Summary for November 25, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

believes that medical urgency can be addressed before it becomes the direst emergency and thereby increase the likelihood that medically urgent candidates can receive a life-saving transplant. The subcommittee members felt, based on their medical judgment and clinical experience, candidates that had completely exhausted dialysis access would only have between 7-14 days to receive a transplant in order to survive, whereas candidates with "imminent risk" of losing dialysis could possibly extend that window for several weeks.²³

The subcommittee began their deliberation with the definition borne out of public comment feedback from the first cycle, which indicated that candidates should have lost vascular access to dialysis. Subcommittee members felt strongly that peritoneal access via the abdomen should also be attempted and failed or else otherwise contraindicated in order to qualify as medically urgent.²⁴ They expanded the definition of vascular access to ensure that attempts had failed or are imminently failing in both upper extremities as well as both lower extremities.

The subcommittee believes that, in addition to the exhaustion of vascular and peritoneal access, candidates must also have pursued dialysis via one additional method.²⁵ These methods define "imminent loss" within the definition of medical urgency and allow for candidates that still have some dialysis access (though not through vascular methods in the upper and lower extremities of peritoneal access through the abdomen) to receive the priority classification.²⁶ It is also possible that this additional method has been pursued and also exhausted, in which case the candidate's condition represents complete loss of dialysis and also qualifies for medical urgency priority.

Classification and Priority Considerations

By creating a new classification within kidney allocation tables, the subcommittee recognized that it would have to consider medical urgency priority in relation to other high-priority classifications. Additionally, subcommittee members would have to determine if medically urgent priority should extend outside of the 250 NM allocation circle, to national offers. Other questions that required discussion included whether the classification could apply to KP candidates seeking isolated kidneys, how multiple medically urgent candidates would be prioritized if they appeared on the same match run, and how the medically urgent classification would be applied to candidates with higher priority classifications.

Having established the definition of medical urgency to apply to candidates with "imminent" loss of dialysis access in addition to those that have completely exhausted all vascular and peritoneal access, the subcommittee agreed that the medical urgency classification should not be placed at the top of each allocation table by sequence. Specifically, subcommittee members wanted to ensure that for Sequence A and Sequence B allocation tables, the medically urgent classification did not receive a higher priority than local pediatric candidates.²⁷ Upon review of the originally proposed classification priority

²³ Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

²⁴ Ibid.

²⁵ Meeting Summary for December 9, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

²⁶ Ibid.

²⁷ Ibid.

placement, present in the first round of public comment, the subcommittee believed that the initially proposed placement was appropriate and should continue to differ by KDPI sequence.²⁸

Because the subcommittee is proposing that the medical urgency priority should not appear as the first sequence in each allocation table, members sought to clarify how a candidate with a priority higher than medical urgency would appear on a match run should they also be classified as medically urgent. For example, if a Sequence A donor kidney became available, how would a local pediatric candidate (Classification 6) that is also medically urgent (Classification 7) appear on a match run? Subcommittee members agreed that said candidate should appear on the match run according to the highest priority classification that they possess, so the local pediatric medically urgent candidate would be appear on the match run based on their Classification 6 priority.²⁹

The subcommittee also considered whether separate medical urgency classifications should be created in order to also give medically urgent candidates registered outside of the 250 NM circle around the donor hospital any priority.³⁰ Under current medical urgency policy, medically urgent candidates only receive priority within the DSA, assuming that all programs within that DSA have agreed to that candidate's priority.³¹ The subcommittee sought to mirror current policy as much as possible and maintain the efficient placement of organs seen in current policy, and so they believed that medical urgency priority should not be extended beyond the initial allocation unit of 250 NM.

The subcommittee considered the question of whether proposed medical urgency policy should apply to en bloc kidney offers. Members noted that new en bloc policy allows transplant programs to opt-in to accepting offers for these kidneys and that one of the goals of the en bloc project, in addition to better utilization, was to increase utilization of pediatric en bloc donor kidneys for pediatric candidates.³² The limited available data reviewed by the subcommittee concerning candidates with characteristics similar to those defined by the subcommittee as "medically urgent" indicated that medically urgent candidates are more likely to be pediatric than non-medically urgent candidates. However, nephrologists and surgeons on the subcommittee expressed doubts that a surgeon or nephrologist of a medically urgent candidate would accept an en bloc offer, given their patient's difficult vascular access.³³ The subcommittee ultimately agreed that though it is unlikely that a transplant surgeon or transplant nephrologist of a medically urgent candidate would accept an en bloc offer, concluded that medically urgent candidates could receive en bloc kidney offers.

Finally, the subcommittee felt it was appropriate to consider whether different allocation options should be considered for medically urgent candidates in Hawaii and Puerto Rico.³⁴

³¹ OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at https://optn.transplant.hrsa.gov/ ³² Improving Allocation of En Bloc Kidneys, OPTN Kidney Transplantation Committee, June 2017. Available at https://optn.transplant.hrsa.gov/

³³ Meeting Summary for December 9, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

²⁸ Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

²⁹ Meeting Summary for November 18, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

³⁰ Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

³⁴ Ibid.

This consideration primarily stems from a policy proposal from the OPTN Liver and Intestines Transplantation Committee which treats medically urgent candidates within Hawaii and Puerto Rico differently, with their own larger allocation circle that ensures that they have access to donor liver offers on the mainland. The subcommittee noted that their medical urgency policy is fundamentally different from the proposed liver policy in one significant way. In DSA-based liver allocation policy, candidates that were medically urgent in Hawaii and Puerto Rico had access to offers within their region, which allowed them to get offers from the mainland. When DSA and region were removed from liver policy in favor of acuity circles, these candidates lost that regional access and thus no longer had priority for offers outside of their respective island territories.³⁵ The OPTN Liver and Intestines Transplantation Committee proposed larger circles for Hawaii and Puerto Rico in order that they would not significantly lose access to mainland offers as a result of moving from a DSA and region-based allocation system to a system utilizing acuity circles.³⁶

Under current kidney policy, candidates in Hawaii and Puerto Rico only receive priority within their respective DSAs, which do not extend to the mainland. This priority would remain unchanged in a kidney allocation system based on an original allocation unit of 250 NM fixed-distance circle with the donor hospital at its center. Therefore, the subcommittee decided that medical urgency priority would apply only to candidates within the initial 250 NM circle across all 50 states and Puerto Rico.³⁷

Evaluation and Oversight Considerations

In developing a consistently applied definition of medical urgency and a method by which candidates can obtain allocation priority by meeting the outlines clinical criteria, the subcommittee sought to impose as little additional administrative data burden as feasible. Members recognized that some oversight is appropriate to ensure that the new classification is being used for its intended purposes, however, they did not want to create a system that was too burdensome for a candidate in the event that they meet the definition for medical urgency, as their time to receive a lifesaving transplant is limited.

The subcommittee explored a few options for evaluation in oversight, but ultimately worked backwards from the Committee's original proposal, which considered a 4-day prospective subcommittee review before the classification would be awarded.

In discussions with UNOS IT and Organ Center concerning the time and resources necessary to conduct a prospective review, the subcommittee determined that it didn't want to pursue an option that would cause a medically urgent candidate any delay in receiving their priority classification, assuming they met the definition.³⁸

³⁵ OPTN Policy Notice Liver and Intestine Distribution Using Distance from Donor Hospital, OPTN Liver and Intestinal Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

³⁶ Access for Urgent Liver Candidates in Hawaii and Puerto Rico, OPTN Liver and Intestinal Transplantation Committee. Available at https://optn.transplant.hrsa.gov/

³⁷ Ibid.

³⁸ Meeting Summary for November 18, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

Instead, the subcommittee worked with staff from the UNOS Organ Center representatives, to develop a retrospective system that would assure center compliance with the definition, allow for adequate post-implementation evaluation, and grant the Committee oversight over the utilization of the classification.

Data Collection

New data collection would only be necessary for members seeking to grant medically urgent priority that has exhausted or will imminently exhaust all dialysis access. Transplant programs will no longer be required to seek permission from other transplant programs within their DSA in order to obtain medical urgency priority for candidates meeting the definition of medical urgency.

The subcommittee was conscious to ensure that any additional data elements aligned with the vision statement and Principles of Data Collection of the OPTN Data Advisory Committee in order to ensure that all elements are necessary and justified.^{39,40,41}

The Committee proposes that the medical urgency classification should be applied to a candidate's listing only after new data fields on waitlist data collection instrument are completed. These fields ensure that the candidate meets the clinical definition of medical urgency as proposed by the Committee. These fields would appear when a new "Medically Urgent" patient status on the waitlist form is selected. The fields require indication that the patient has exhausted or otherwise contraindicated all forms of access listed in the medical urgency definition. The candidate's transplant surgeon and transplant nephrologist must review and sign a written approval of the candidate's exhausted vascular and peritoneal dialysis access and the imminent loss of dialysis access via additional methods listed in policy. The transplant hospital must document this approval in the candidate's medical record and submit both documents to the OPTN within seven (7) business days.

The subcommittee continually updated the OPTN Data Advisory Committee (DAC) of their progress in developing necessary new data collection, the DAC endorsed the proposal at their meeting on December 9, 2019.

Potential Impact on Select Patient Populations

This proposal is projected to affect very few kidney and kidney-pancreas candidates in total; however, those candidates that are affected will see a significant impact in terms of priority in allocation. Available data suggest that this policy could be applied as many as 100 times annually, which reflects less than one percent of total kidney transplants. Candidates that meet the definition for medical urgency will see increased priority in allocation. Furthermore, candidates from small DSAs may see the range of their priority expanded, as it now extends to 250 NM from the donor hospital in all directions. Conversely, candidates from very large DSAs with policies for medical urgency may see the range of their priority diminished, as their DSAs may have been larger than 250 NM. Finally, because of the placement of the classification below classifications for inside-the-circle pediatric candidates, living donor candidates and the most highly-sensitized candidates, this policy proposal is not expected to significantly affect these candidate populations.

³⁹ Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

⁴⁰ Data Advisory Committee Charge. Available at https://optn.transplant.hrsa.gov/

⁴¹ Data Advisory Committee Principles for Data Collection. Available at https://optn.transplant.hrsa.gov/

Implementation and Operational Considerations

Overview

Overall, implementation and operational considerations are minimal for this policy proposal. Some IT programming is required, as well as some additional document maintenance to maintain records of supporting documentation received by the OPTN.

OPTN Actions

Programming changes will be required to implement a new Medically Urgent classification. Changes will be made to the Kidney allocation systems and to candidate's waitlist record in order to add the medically urgent classifications. UNOS will follow established protocols to inform members and provide educational materials regarding any policy changes.

The OPTN will maintain and secure all submitted supporting documentation for retrospective review of the OPTN Kidney Transplantation Committee.

Member Actions

Member actions are anticipated to be very minimal, as the new policy affects a very low-volume candidate population. New data collection requirements are nominal and merely represent a codification in OPTN policy of practices that many transplant programs are conducting for this candidate population within their respective DSAs.

Post-implementation Monitoring

Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. The OPTN Contractor may review any data entered in UNet[™], and members are required to submit documentation as requested.

Policy Evaluation

This policy will be formally evaluated approximately 3 months, 6 months, 1 year, and 2 years post-implementation.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- How many registrations receive medical urgency allocation priority?
- What were the characteristics of medically urgent candidates and donor kidneys received by them?
- What were the waiting list outcomes of registrations receiving medically urgent allocation priority?
- What were the post-transplant outcomes of medically urgent transplant recipients?
- How long do candidates wait in medically urgent status before receiving a transplant?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to pre- and post-policy implementation:

Overall and by OPTN Region:

- #/% of candidates on the WL that received medically urgent allocation priority (also by candidate characteristics such as CPRA (%), EPTS (%), age group, primary vs. repeat transplant, dialysis vintage)
- Distribution of time in medical urgency classification before WL removal (min, q25, mean, sd, median, q75, max)
- #/% by WL removal reason for registrations in medical urgency status
 - Competing risk median time to transplant
 - #/% of medically urgent deceased donor kidney transplant recipients by KDPI sequence (0-20%, 21-34%, 35-85%, 86-100%)
- National unadjusted post-transplant graft and patient survival for medically urgent transplant recipients (compared to non-medically urgent transplants)
- National DGF rates for medically urgent transplant recipients (compared to non-medically urgent transplants)

Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed "in accordance with §121.4", which in turn incorporates the requirements in §121.8 that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal addressing the following requirements of the Final Rule:

- Shall be based on sound medical judgment: The Committee proposes this change based on the medical judgment that candidates with complete loss or imminent loss to dialysis access should receive allocation priority to address their medical urgency.
- Shall seek to achieve the best use of donated organs: The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to make the best use of donated organs by using them for the most medically urgent candidates when they have exhausted dialysis access.
- Shall be designed to... promote patient access to transplantation: This proposal seeks to promote access to transplant for the most medically urgent candidates on the kidney transplant waiting list.
- Shall not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]: This proposal presents a uniform, consistent policy that is standardized across the country. Whereas, under previous policy, the definition of a medically urgent candidate could vary DSA-by-DSA, there is now one proposed national definition, which removes variability based on a candidates place of listing.

- Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program: This proposal includes mechanisms for retrospective review and oversight to ensure the new medical urgency classification is utilized appropriately.
- Shall be reviewed periodically and revised as appropriate: The Committee has outlined postimplementation evaluation strategies to allow for necessary changes to be made based on the execution of the proposed policy in the new kidney allocation framework.

Although the proposal outlined in this policy proposal addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
- Shall be designed to avoid wasting organs, to avoid futile transplants, ... and to promote the efficient management of organ placement;

Conclusion

The Committee's proposal seeks to provide a rationally determined and consistently applied definition for medical urgency in order that candidates with imminent failure of access to dialysis can receive the appropriate priority in an expedient manner while still allowing for retrospective oversight. One of the guiding principles of the subcommittee's evidence-gathering process and deliberations was to try to mirror the current policy and practices of transplant programs within the new allocation environment. This would serve to reduce additional administrative burden or fiscal impact of the proposal and maintain the efficient placement of organs in accordance with the OPTN Final Rule while still maintaining a mechanism for medically urgent candidates to receive appropriate priority in allocation.⁴² Committee members believe that their definition for medical urgency and proposal for implementation is appropriate based on these goals and principles and is a product of sound medical judgement, evidence-gathering, and community feedback.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding the following:

- 1. Do you believe any additional criteria should be added to or removed from the definition of "medical urgency" as proposed by the Committee?
- 2. Do you believe that the new medical urgency classification should receive priority outside of the 250 NM circle? Should medically urgent candidates outside of the circle receive priority before non-medically urgent candidates inside of the circle?
- 3. A new medical urgency classification has been included in each KDPI category for kidney allocation. The Committee requests feedback on the proposed prioritization within each sequence.
- 4. What types of supporting documentation do you believe are appropriate to ensure the medically urgent classification is being utilized as intended?

⁴² 42 C.F.R. § 121.8.

OPTN

Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (example). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

Policy 8: Allocation of Kidneys

2 8.2 Exceptions

3	8.2.A	Exceptions Due to Medical Urgency
4 5	To qualify for n	nedically urgent priority in allocation, both the candidate's transplant nephrologist and
6		geon must confirm medical urgency based on meeting the following criteria:
7		
8	<u>First, the candi</u>	date must have exhausted, or has a contraindication to, all dialysis access via all of the
9	following meth	nods:
10	• <u>Va</u>	scular access in the upper left extremity
11	• <u>Va</u> :	scular access in the upper right extremity
12	• <u>Va</u>	scular access in the lower left extremity
13	• <u>Va</u>	scular access in the lower right extremity
14	• <u>Pe</u>	ritoneal access in the abdomen
15		
16		on or contraindication to all dialysis via the methods listed above, the candidate must also
17		nausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the
18	following meth	nods:
19	• <u>Tra</u>	anshepatic IVC Catheter
20	• <u>Tra</u>	anslumbar IVC Catheter
21	• <u>Ot</u>	her method of dialysis (must specify)
22		
23		s transplant surgeon and transplant nephrologist must review and sign a written approval
24 25		te's qualification for medical urgency, based on the criteria above. The transplant hospital
25 26		It this medical urgency qualification in the candidate's medical record and submit cumentation to the OPTN within seven business days of indicating medical urgency status.
20 27		ssified as medically urgent may be retrospectively reviewed by the Kidney Transplantation
28		ses may be referred to Membership & Professional Standards Committee (MPSC) for
29		ng to Appendix L of the OPTN Bylaws.
30		
31	8.5	Kidney Allocation Classifications and Rankings
32	8.5.C	Sorting Within Each Classification
33		
34	Within	each classification that is not a medically urgent classification, candidates are sorted in
35	the fol	lowing order:
36		
37		I points (highest to lowest)
38	2. Date	e and time of the candidate's registration (oldest to most recent)

39 40 41	Within each medically urgent classification, candidates are sorted in the following order:
42	1. Total waiting time at medically urgent status (highest to lowest)
43	2. <u>Total points (highest to lowest)</u>
44	3. Date and time of the candidate's registration (oldest to most recent)
45	
46	8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to
47	20%
48	Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or
49	equal to 20% are allocated to candidates according to <i>Table 8-6</i> below.
50	
51	Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
2	Medically Urgent	<u>250NM</u>	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>8</u>	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
<u>9</u>	CPRA equal to 99%, blood type identical or permissible	250NM	Any
<u>10</u>	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	CPRA equal to 98%, blood type identical or permissible	250NM	Any
<u>12</u>	0-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
<u>13</u>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<u>14</u>	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<u>15</u>	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Nation	Any
<u>16</u>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>17</u>	0-ABDR mismatch, top 20% EPTS, and blood type B	250NM	0
<u>18</u>	O-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	Nation	0
<u>19</u>	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
<u>20</u>	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	Nation	0
21	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
22	0-ABDR mismatch, top 20% EPTS, and blood type permissible	250NM	Any
23	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<u>24</u>	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>25</u>	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Nation	Any
<u>26</u>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<u>27</u>	Top 20% EPTS, blood type B	250NM	A2 or A2B
<u>28</u>	Top 20% EPTS, blood type permissible or identical	250NM	Any
<u>29</u>	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
<u>30</u>	O-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<u>31</u>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<u>32</u>	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	0
<u>33</u>	O-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	0

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>34</u>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
<u>35</u>	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	250NM	Any
<u>36</u>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<u>37</u>	O-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<u>38</u>	EPTS greater than 20%, blood type B	250NM	A2 or A2B
<u>39</u>	All remaining candidates, blood type permissible or identical	250NM	Any
<u>40</u>	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
<u>41</u>	Top 20% EPTS, blood type B	Nation	A2 or A2B
<u>42</u>	Top 20% EPTS, blood type permissible or identical	Nation	Any
<u>43</u>	All remaining candidates, blood type permissible or identical	Nation	Any

8.5.1 Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-7* below.

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
<u>7</u>	Medically Urgent	<u>250NM</u>	<u>Any</u>
<u>8</u>	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
<u>9</u>	CPRA equal to 99%, blood type permissible or identical	250NM	Any

Table 8-7: Allocation of Kidneys from Deceased Donorswith KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>10</u>	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
<u>11</u>	CPRA equal to 98%, blood type permissible or identical	250NM	Any
<u>12</u>	0-ABDR mismatch, blood type identical	250NM	Any
<u>13</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<u>14</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
<u>15</u>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
<u>16</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<u>17</u>	0-ABDR mismatch, blood type B	250NM	0
<u>18</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	0

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>19</u>	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	0
20	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	0
<u>21</u>	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
22	0-ABDR mismatch, blood type permissible	250NM	Any
<u>23</u>	O-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<u>24</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any
<u>25</u>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
<u>26</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>27</u>	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G:</i> <i>Prioritization for Liver</i> <i>Recipients on the Kidney</i> <i>Waiting List,</i> blood type permissible or identical	250NM	Any
<u>28</u>	Blood type B	250NM	A2 or A2B
<u>29</u>	All remaining candidates, blood type permissible or identical	250NM	Any
<u>30</u>	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
<u>31</u>	Blood type B	Nation	A2 or A2B
<u>32</u>	All remaining candidates, blood type permissible or identical	Nation	Any

8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-8* below and the following:

- Classifications 1 through 30 for one deceased donor kidney
- Classifications 31 and 32 for both kidneys from a single deceased donor

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
<u>6</u>	Medically Urgent	<u>250NM</u>	<u>Any</u>
2	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
<u>8</u>	CPRA equal to 99%, blood type permissible or identical	250NM	Any
<u>9</u>	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
<u>10</u>	CPRA equal to 98%, blood type permissible or identical	250NM	Any

29

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
11	0-ABDR mismatch, blood type identical	250NM	Any
<u>12</u>	O-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<u>13</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
<u>14</u>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
<u>15</u>	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<u>16</u>	0-ABDR mismatch, and blood type B	250NM	0
<u>17</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	0
<u>18</u>	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	0
<u>19</u>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	0

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>20</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
<u>21</u>	0-ABDR mismatch, blood type permissible	250NM	Any
22	O-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<u>23</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any
<u>24</u>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any
<u>25</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<u>26</u>	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G</i> : <i>Prioritization for Liver</i> <i>Recipients on the Kidney</i> <i>Waiting List</i> , blood type permissible or identical	250NM	Any
<u>27</u>	Blood type B	250NM	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>28</u>	All remaining candidates, blood type permissible or identical	250NM	Any
<u>29</u>	Blood type B	Nation	A2 or A2B
<u>30</u>	All remaining candidates, blood type permissible or identical	Nation	Any
<u>31</u>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
<u>32</u>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% are allocated to adult candidates according to *Table 8-9* below and the following:

- Classifications 1 through 21, 23 and 24 for one deceased donor kidney
- Classifications 22 and 25 for both kidneys from a single deceased donor

Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
<u>5</u>	Medically Urgent	<u>250NM</u>	<u>Any</u>
<u>6</u>	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
Z	CPRA equal to 99%, blood type permissible or identical	250NM	Any
<u>8</u>	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
<u>9</u>	CPRA equal to 98%, blood type permissible or identical	250NM	Any
<u>10</u>	0-ABDR mismatch, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>11</u>	O-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
12	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<u>13</u>	0-ABDR mismatch, blood type B	250NM	0
<u>14</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	0
<u>15</u>	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
<u>16</u>	0-ABDR mismatch, blood type permissible	250NM	Any
17	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any
<u>18</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<u>19</u>	Prior liver recipients that meet the qualifying criteria according to Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, blood type permissible or identical	250NM	Any
<u>20</u>	Blood type B	250NM	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>21</u>	All remaining candidates, blood type permissible or identical	250NM	Any
22	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
<u>23</u>	Blood type B	Nation	A2 or A2B
<u>24</u>	All remaining candidates, blood type permissible or identical	Nation	Any
<u>25</u>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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