OPTN

Briefing to the OPTN Board of Directors on

Addressing Medically Urgent Candidates in the New Kidney Allocation System

OPTN Kidney Transplantation Committee

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Addressing Medically Urgent Candidates in the New Kidney Allocation System

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Sponsoring Committee:	*Kidney Transplantation*
Public Comment Period:	*January 22, 2020 – March 24, 2020*
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Executive Summary

Currently, candidates that are considered "medically urgent" are considered "exceptions" to kidney allocation policy by allowing candidate's transplant physician to use medical judgment to transplant a candidate out of sequence due to medical urgency.[1] If there is more than one kidney transplant program in the same DSA, then the candidate's physician must seek agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence. These current medical urgency policies were removed when the OPTN Board of Directors adopted new kidney policies that remove DSA as a unit of allocation.[2]

The OPTN Kidney Transplantation Committee (the Committee) proposes the creation of a "Medically Urgent" classification within all kidney allocation tables. The classification creates priority for candidates 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 kidney donor profile index (KDPI) sequences in allocation policy. The Medical Urgency classification grants medically urgent candidates increased priority within the 250 NM distribution circle only. However, in classifications with a higher priority than the Medical Urgency classification in allocation tables, a

[1] OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at https://optn.transplant.hrsa.gov/
[2] Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at https://optn.transplant.hrsa.gov/

candidate that is medically urgent will be prioritized over non-medically urgent candidates in those classifications, including mandatory national shares for 100% highly-sensitized candidates. The Committee proposes new medical eligibility criteria that would qualify candidates for additional priority via the new classification. 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.

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.

Background

Prior to the OPTN Board of Directors adoption of new kidney allocation policies,[3] which removed DSA and region as units of distribution and implemented a 250 nautical mile (NM) fixed-distance circle; candidates that were considered "medically urgent" were considered exceptions to allocation policy. Specifically, Policy 8.2.A "Exceptions Due to Medical Urgency" states 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."[4] 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."

Following the OPTN Board of Directors approval of new kidney allocation policies to remove DSAs and regions as units of distribution in allocation,[5] which eliminated Policy 8.2.a: Exceptions Due to Medical Urgency, the OPTN Kidney Transplantation Committee formed the Medical Urgency Subcommittee (the Subcommittee) to further evaluate if a medial urgency priority policy was necessary and, if so, how to retain priority for medically urgent candidates in a new system of allocation.

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 outcomes can be expected for candidates that receive a transplant via medical urgency policy?

Because medical urgency exceptions are currently managed and approved at the DSA level and operate as exceptions to the match run, data on the number of candidates that have been transplanted via medical urgency exceptions and the number of candidates currently listed as medically urgent are not available.

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 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

[3] Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at https://optn.transplant.hrsa.gov/
[4] OPTN Policy 8.2.A Exceptions Due to Medical Urgency. 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/

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 Subcommittee 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.[6,7] Generally, international medical urgency assignment tends to include 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.

The Subcommittee 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, and the greater OPTN Kidney Transplantation Committee, set forth to develop a standardized, medically sound, and sensible proposal that addressed the following:

- A definition of medical urgency within kidney allocation policy
- The creation and priority placement of a medical urgency classification within kidney allocation tables
- An oversight and documentation process to monitor use of new medical urgency priority

Purpose

The OPTN Final Rule grants the OPTN the authority to develop "policies for the equitable allocation for cadaveric organs…"[8] The Committee's proposal seeks to provide a rationally determined and consistently applied definition for medical urgency in order that candidates that have exhausted dialysis access, as well as candidates with imminent failure of access to dialysis, can receive the appropriate priority in an expedient manner while still allowing for retrospective oversight. The Committee's recommendation to continue to provide priority to candidates that meet the proposed definition of medical urgency is grounded in the OPTN Final Rule performance goal that the OPTN allocation policies Set "priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants" that are "ordered from most to least medically urgent."[9]

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

[6] 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/

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

[8] 42 C.F.R. § 121.4 (a) (1)

[9] 42 C.F.R. § 121.8 (b) (3)

still maintaining a mechanism for medically urgent candidates to receive appropriate priority in allocation.[10] Committee members believe that their definition for medical urgency and proposed solution for implementation is appropriate based on these goals and principles and is a product of sound medical judgement, evidence-gathering, and community feedback.

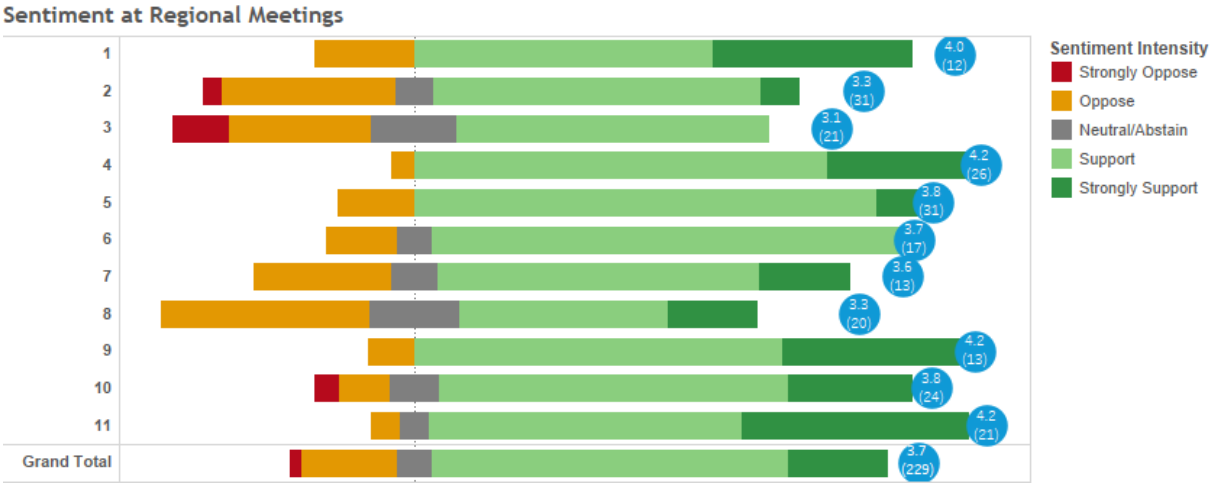
Overall Sentiment from Public Comment

The Committee submitted their proposal "Addressing Medically Urgent Candidates in New Kidney Allocation Policies" for consideration and community feedback during the OPTN Winter 2020 Public Comment period. This Public Comment period opened on January 22nd, 2020 and closed on March 24th, 2020. Community members were able to submit comments individually on the OPTN website or by email and fax. Individual and regional sentiment and feedback was collected at each of the 11 OPTN Regional Meetings as well as during OPTN Committee meetings.

Regional meetings for Region 9, Region 10, and Region 11 were conducted virtually via webinar in order to follow Centers for Disease Control (CDC) guidance that discouraged large gatherings in order to prevent the spread of the COVID-19 virus.[11]

Sentiment for the proposal received at each of the OPTN Regional Meetings is highlighted in Figure 1 below.[12]

Figure 1: Proposal Sentiment at OPTN Regional Meetings



The proposal prompted robust discussion at every regional meeting. While sentiment reflects support across each of the eleven regions, each regional meeting featured conversation and feedback about changes that the committee should consider in their final proposal to the OPTN Board of Directors. The

[10] 42 C.F.R. § 121.8.

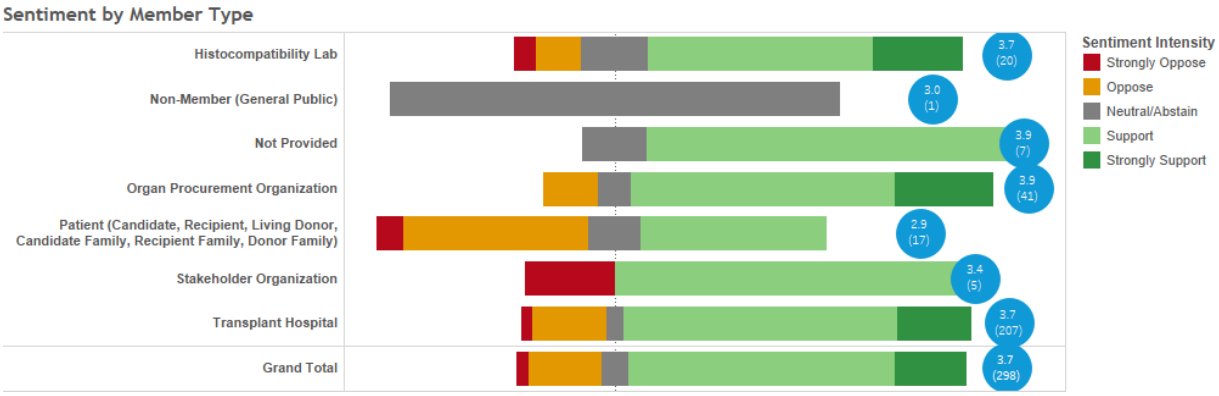
[11] "Get Your Mass Gatherings or Large Community Events Ready." Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, March 14, 2020. https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/mass-gatherings-ready-for-covid-19.html. (accessed March 9, 2020).

[12] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

themes of feedback received at OPTN Regional meetings mirrored feedback received from the greater community and are highlighted in the upcoming section titled, “Community Feedback Themes.”

In addition to voting on the proposal as written, Region 2 and Region 8 took separate votes on a proposal amendment that would replace the retrospective review process with a prospective review process. In a prospective review process, a candidate would not receive additional allocation priority until their case was evaluated and approved by a newly-established review body. These amendments received stronger support in Region 2 and Region 8 than the proposal as written.
When sorted by member type, the community sentiment appears somewhat similarly, leaning more positively overall with pockets of opposition and an abundance of feedback. Sentiment by OPTN member type is illustrated in **Figure 2** below:[13]

Figure 2: Proposal Sentiment by Member Type



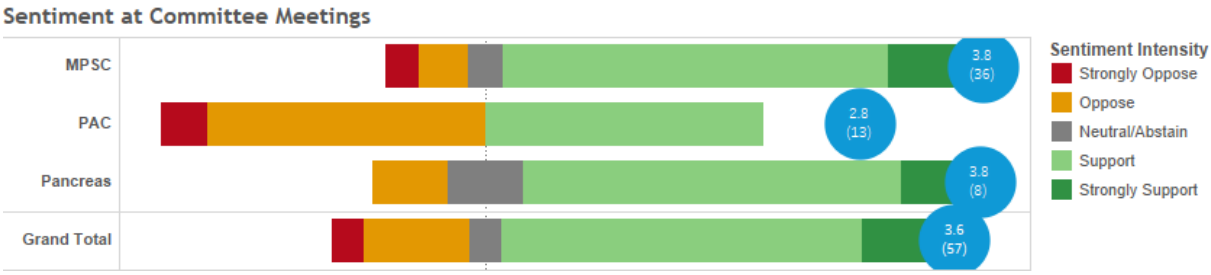
Approximately 71% of the feedback received came from transplant hospital representatives, whose sentiment was mostly in support, but who also provided valuable constructive feedback for the proposal.

The patient community was divided in their sentiment towards the proposal. Feedback from patients centered on the proposed priority of the medical urgency classification.[14] This feedback is further explained in the section below titled, “Community Feedback Themes.”

In addition to public feedback, the Committee presented the proposal to three OPTN committees to gather their sentiment and narrative response. Sentiment of the OPTN Membership and Professional Standards Committee (MPSC), the OPTN Patient Affairs Committee (PAC) and the OPTN Pancreas Transplantation Committee are illustrated in **Figure 3** below.[15]

[13] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.
[14] February 20, 2020, OPTN Patient Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[15] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for committees only includes attendees at that committee meeting. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Figure 3: Proposal Sentiment by OPTN Committees



Much like sentiment at regional meetings and sentiment by member type, the sentiment of the OPTN Committees was mostly positive, with some opposition and an abundance of useful feedback for the Committee to consider when finalizing their proposal for OPTN Board consideration.

Notably, a majority of the OPTN Patient Affairs Committee did not support the proposal as written. Furthermore, the committee expressed mixed sentiment on how the oversight of the classification should be conducted, with some members stating there should be no delay in receiving priority if a candidate meets the definition of medical urgency, and others believing that a case should receive review and approval before additional allocation priority is awarded. In addition, committee members had different views on the priority placement of the classification, with some living donors suggesting that a medically urgent candidate should receive higher priority than a living donor in stable condition.

Feedback and sentiment from the OPTN MPSC was also significant, as they may review medical urgency cases when a retrospective review is conducted by the Committee. The MPSC supported the proposal as written and also recommended that additional priority be given to medically urgent local pediatric candidates, above non-medically urgent local pediatric candidates.[16]Furthermore, the OPTN MPSC suggested that, considering that medically urgent candidates are likely to have higher EPTS scores, it may be prudent not to include medically urgent priority for Sequence A in allocation, which "is preferentially directed toward candidates with lower EPTS scores and higher post-transplant survival."[17] Also, the OPTN MPSC referenced consideration of a prospective review process and suggested that higher allocation priority could be considered if these candidates are rare.[18]

The OPTN Pancreas Committee reviewed the proposal at their February 19th, 2020 meeting. Members inquired as to the number of medically urgent candidates that were highly sensitized, and if priority only within the 250NM circle would be enough to give these candidates the appropriate priority if they met the proposed definition. A member inquired if there was a way to consider risk of complication when calculating the scores for allocation without penalizing the transplant centers. The Committee believes that such considerations would be more viable to consider during the development of the continuous distribution allocation framework.[19]

[16] February 20, 2020, OPTN Patient Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[17] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[18] *Ibid.*
[19] February 19, 2020, OPTN Pancreas Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

Community Feedback Themes

Community feedback and suggested changes to the proposal primarily fell into three major themes, which define the mechanisms of the proposed policy: the definition of medical urgency, the priority of the classification in allocation, and the oversight process.

Definition of Medical Urgency

The community at large had a range of feedback and a robust conversation concerning the Committee's proposed definition for a medically urgent candidates. The American Society of Transplant Surgeons (ASTS), supported the definition as proposed, stating that it, "defines the criteria for medical urgency in kidney transplantation in a more comprehensive and coherent fashion to address the needs of these unique patients."[20] The American Nephrology Nurses Association (ANNA) also supported the proposal as written.[21]

However, others in the community were concerned with the inclusion of definition characteristics that represent a candidate's imminent loss of dialysis access. Specifically, some in the community were concerned about how transplant programs may change their organ acceptances practices for candidates being dialyzed via translumbar or tranpheapatic IVC catheter, because those candidates would receive the higher priority but would be in the same classification as candidates not being dialyzed in that way who potentially could not afford to wait longer. Some members of the patient community were concerned about these candidates with stable dialysis access via catheter would receive greater priority than candidates in lower priority classifications that might have accrued significantly more wait time. Additionally, some member institutions suggested that they do not currently have staff with expertise in translumbar and transhepatic IVC catheter application.

Another significant piece of feedback received concerning the proposed medical urgency definition centered on its lack of applicability to pediatric candidates. Specifically, several community members stated that pediatric patients are poor candidates for lower extremity dialysis access and should be addressed more directly in the definition. The American Society for Transplantation (AST) stated that, "The criteria for medically urgent status as listed in the proposal are focused on adult criteria given that many of the criteria (e.g.; leg graft access) are not feasible or even possible in small children. We suggest consideration be given to development of pediatric criteria or at least modification of the proposal to indicate that the proposed criteria only applicable to adults."[22] Though the Committee had considered this variable in their deliberations, the members felt that these candidates would simply contraindicate to this access, as is permissible via the proposed definition.[23]

Some practitioners in the community stated that they have never seen an instance of complete exhaustion of dialysis access and suggested that perhaps a "medical urgency" definition and classification aren't necessary.

[20] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[21] *Ibid.*
[22] *Ibid.*
[23] Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/

Priority of Medical Urgency Classification

The proposed placement of the medical urgency classification within each of the four sequences in the kidney allocation tables received less variability in community sentiment and feedback when compared to the overall definition and proposed oversight process.

First, nearly all commenters that addressed the proposal that medical urgency priority only apply within the 250NM allocation circle agreed with the approach. Three societies, including ASTS, AST, and The Organization for Transplant Professionals (NATCO) specifically expressed their approval for this limited priority in their comments on the OPTN Public Comment site.[24] In a separate letter to Committee leadership following the conclusion of the Public Comment period, the Association of Organ Procurement Organizations (AOPO) also stated their support for classification priority existing only within the 250NM allocation circle.[25]

There were some slight differences in opinion as it concerns the proposed priority placement of the allocation, which is illustrated in Figure 4 below:

Figure 4: Proposed Priority of Medical Urgency Classification by Sequence

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)

For example, members of the OPTN PAC debated whether the medical urgency classification should be placed above inside circle prior living donors, specifically in Sequence C.[26] Similarly, members at the virtual OPTN Region 10 meeting discussed the idea that inside circle medically urgent candidates should be placed at the top of the allocation priority in Sequence D, as these candidates are in need of any compatible kidney to save their life.[27]

[24] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[25] Ranum, Kelly. "AOPO Comments." Email message to Shannon Edwards, March 30, 2020.
[26] February 20, 2020, OPTN Patient Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[27] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

An additional suggestion that received significant discussion throughout the public comment period is that medically urgent pediatric candidates should be prioritized over non-medically urgent pediatric candidates in Sequences A and B. The Subcommittee discussed the possibly of intra-classification priority for medically urgent candidates in those classifications with higher priority than the proposed medical urgency classification; however, they initially concluded that little value may be added because candidate with these priorities will likely receive an abundance of offers at their given priority level.[28]

Finally, NATCO suggested that an approach that utilizes one classification for "imminent loss" of dialysis access in allocation, and another, higher-priority classification for "complete exhaustion" of dialysis of dialysis access may be preferable. Specifically, NATCO stated, "NATCO recommends a Status 1A classification, similar to that used in liver allocation, could be assigned to candidates who are completely out of dialysis access."[29]

Oversight of Medical Urgency Classification

The oversight and required documentation component of the proposal also received attention from the community.

Most prevalent among the comments were differing perspectives on whether review of the use of the medical urgency classification should be retrospective or prospective.

In the retrospective review process as proposed, a candidate that meets the definition of medical urgency will receive the priority immediately when the transplant program indicates such a status in the Waitlist[SM] data collection tool. Candidates would be required to submit supporting documentation indicating a candidate's medically urgent status within seven (7) business days. The use of this status would be reviewed by the Committee retrospectively and if the Committee felt that the classification was misused, they could refer such an instance to the OPTN MPSC.

Several members and stakeholders in the community did not feel that retrospective oversight of the classification was sufficient enough to deter inappropriate us of the medical urgency status and priority. As previously stated, Region 2 and Region 8 took separate votes on a proposal amendment that would replace the retrospective review process with a prospective review process. In a prospective review process, a candidate would not receive additional allocation priority until their case was evaluated and approved by a newly-established review body. These amendments received stronger support in Region 2 and Region 8 than the proposal as written.

NATCO wrote that their organization, "strongly recommends that the process of retrospective review be replaced with a system of prospective review to include examination of documentation by appropriately qualified physicians appointed to an expert review board, or by a sub-committee of the Kidney Transplantation Committee."[30] Similarly, AST cited a "concern regarding the retrospective nature of the review of the 'Medically Urgent" status."[31]

[28] Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at https://optn.transplant.hrsa.gov/
[29] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[30] *Ibid.*
[31] *Ibid.*

Members of the OPTN PAC expressed arguments both for and against a retrospective review. Some suggested that it they were losing their dialysis access, they wouldn't want to have any delay in receiving their priority. Other members worried that some centers may use the definition of "imminent loss" and the ability to contraindicate to inappropriately prioritize their candidates.[32] The PAC informally proposed the idea that it might be appropriate for a transplant program to receive approval from another "independent" transplant center before priority could be awarded.

It should also be noted that, while conversation around the review process was robust, every OPTN Region voted in favor of the proposal with retrospective review with majority positive sentiment. Region 4 was nearly unanimous in support of the proposal with retrospective review and added that such review should occur in a timely manner.[33] Region 5, which expressed a highly positive sentiment in support of the proposal with a retrospective review, specifically considered how "liver Status 1A"elegibility and priority are reviewed retrospectively."[34]

Both the ASTS and AOPO supported the use of a retrospective review for medically urgent candidates. In their comments, the AOPO stated that it, "supports the proposed criteria for a medically urgent patient as proposed and commends the Kidney Transplantation Committee for establishing a consistent definition to be applied nationally."[35] Furthermore, regarding retrospective case review, the AOPO suggested, "monitoring of the policy change to include the number of candidates listed as medically urgent and the trends in those listings; the number of candidates transplanted as medically urgent; outcomes of such transplants; and the percentage of time any organ allocated under this policy was used in the intended recipient.[36]

In addition to feedback regarding the review process, some organizations offered suggestions for specific forms of supporting documentation that should be considered as requirements for submission. Specifically, the ASTS suggested, "recent notes from interventional radiology or surgery with imaging confirming thrombosis or severe, untreatable stenosis of the vascular structures" and "evidence the candidate has received a translumbar or transhepatic catheter."[37]

Committee Consideration of Public Comment Feedback

The Committee comprehensively reviewed all of the feedback received from the community via OPTN regional meetings, the OPTN Public Comment website, and conversations amongst other OPTN committees. The Committee recognized that the wealth of feedback, both supportive and critical, warranted re-review of each of the components of the proposal before finalization for OPTN Board consideration. The Committee re-evaluated the proposed definition of medical urgency, the priority that the new classification would receive in allocation, and the documentation and oversight process that would assess the utilization of the classification.

[32] February 20, 2020, OPTN Patient Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[33] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[34] *Ibid.*
[35] Ranum, Kelly. "AOPO Comments." Email message to Shannon Edwards, March 30, 2020.
[36] *Ibid.*
[37] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

Medical Urgency Definition

The Committee believes that a standard, national definition of medical urgency, based on current practice in the community, is a more equitable policy for allocating kidneys to candidates across the country, regardless of whether their DSA had procedures for medical urgency priority before.

When re-evaluating the proposed definition, the Committee sought to assess whether their definition represented a balance between a stringent definition that would only represent the very worst clinical case and a lenient definition that might encompass candidates with clinical characteristics that may not be universally be recognized as "urgent."[38] Some Committee members expressed concern that if the definition was too stringent, perhaps by removing the components of the definition that represent "imminent loss," then candidates could die before meeting the definition to receive priority, or they could receive the priority only to die before receiving a compatible organ offer.[39] Conversely, members wanted to ensure that the definition wasn't so lenient that a candidate with a year or more of viable dialysis access would be considered medically urgent.[40]

The component of the definition that received the greatest deliberation was the inclusion of dialysis access methods that represent "imminent loss" of dialysis access. Specifically, the following language:

> "Also, the candidate has exhausted dialysis access, is currently being dialyzed, or has a contraindication to dialysis via one the following methods:
>
> - Transhepatic IVC Catheter
> - Translumbar IVC Catheter
> - Other (must specify method)"[41]

Members of the Subcommittee that initiated development of the proposal reiterated the justification for the inclusion of these methods in the definition for medical urgency. Specifically, members expressed that dialysis via transhepatic IVC catheter and translumbar IVC catheter are "long shot" methods of dialysis access.[42] Members expressed that these are methods of last resort and, as evidenced by some of the community feedback received, are not universally available at every transplant program in the country.[43] Members were confident that in these instances, centers would refer candidates to centers with such expertise or otherwise contraindicate if candidate characteristics dictated as appropriate.[44]

Members are confident that the inclusion of these methods within the definition for medical urgency strike an effective balance between stringency and leniency and also represents a combination of

[38] April 22, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[39] April 02, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[40] *Ibid.*
[41] *Addressing Medically Urgent Candidates in New Kidney Allocation Policy*, OPTN Kidney Transplantation Committee, January 2020, https://optn.transplant.hrsa.gov/governance/public-comment/addressing-medically-urgent-candidates-in-new-kidney-allocation-policy/. (accessed April 28, 2020)
[42] April 22, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[43] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[44] April 02, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

eligibility requirements received from OPOs that was gathered voluntarily during the evidence-gathering phase of policy development.[45]

An additional consideration the Committee debated based on community feedback was whether policy should explicitly indicate that pediatric candidates may contraindicate to lower extremity dialysis access. Members of the committee, including those with direct experience treating pediatric candidates, urge caution in including such explicit language. Committee members recognize that, for example, pediatric candidates at age 4 are very clinically different from pediatric candidates at age 17, and the Committee does not want to intrude upon clinical care with explicit policy language.[46] Members expressed the belief that transplant programs and their vascular surgeons know best as to how to treat their patients and would use their best judgement in making the decision as to whether a pediatric candidate has viable lower extremity dialysis access. The Committee chose not to include specific information about pediatric candidate contraindication within policy language, but agreed such clarifications may be appropriate for associated educational material as well as outlined in the Waitlist[SM] data submission tool if the policy were to be implemented.[47]

In the original proposal, medical urgency would only apply to registered candidates in active status on the kidney waiting list. After receiving community feedback and further considering the definition, the Committee decided to make eligibility requirements more explicit. Specifically, Committee members agreed that a candidate should be eligible for primary waiting time in order to be eligible to receive medical urgency priority.[48]

The definition of medical urgency requires that a candidate exhaust or contraindicate to dialysis access via several methods. To qualify for primary waiting time, an adult candidate must have begun regularly administered dialysis or have a a qualifying estimated glomerular filtration rate (eGFR). Therefore, the only possible scenario where a candidate didn't qualify for primary waiting time but could qualify for medical urgency priority were if candidate contraindicated to all forms of dialysis access and also didn't have a qualifying eGFR.

The Committee agreed that if a candidate contraindicated to all forms of dialysis access but didn't have a qualifying eGFR, they should not be eligible to receive medical urgency priority. Therefore, the Committee proposes specifying that a candidate must be eligible for primary waiting time in order to be eligible to receive medical urgency priority.

Having considered the community feedback, the Committee is introducing one post-public comment changes to the definition of medical urgency. Specifically, the definition clarifies that candidates must be eligible for waiting time under OPTN Policy 8.4 in order to qualify for medical urgency classification priority. The Committee feels this is necessary because it is possible for a candidate to be active on the waiting list but not accrue primary wait time because they have not begun regularly administered dialysis or have a qualifying eGFR.

[45] April 22, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[46] April 22, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[47] *Ibid.*
[48] April 20, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

Medical Urgency Classification

Classification Priority Placement

The Committee reviewed the limited feedback that was received concerning the priority placement of the Medical Urgency classification. There were some considerations for priority, based on the feedback solicited by the Committee in the public comment proposal, which prompted discussion and resulted in direct amendments to the proposal.

The Committee felt assured in the priority placement within each of the KDPI allocation sequences based on the feedback received during the Public Comment period. The Committee briefly considered feedback that the classification should not be present in KDPI sequence A or should have the highest priority in Sequence D, but agreed that the community sentiment of the priority placement illustrated that their initial proposal was the most medically appropriate and acceptable to the community at large.

One consideration, raised by the OPTN Pediatric Committee, the OPTN MPSC, and others that garnered significant attention from the Committee was that under the proposed language, there is not an avenue for a medically urgent pediatric candidate within the 250NM allocation circle to receive additional priority over a non-medically urgent pediatric candidate within the same 250NM allocation circle.[49] This is because in the proposed policy, the medical urgency classification had a lower priority than the pediatric candidate within the 250NM allocation circle.

The Committee agreed that within the 250NM allocation circle, creating a pathway for a medically urgent pediatric candidate to receive priority over a non-medically urgent pediatric candidate within that classification should be added to the proposal for Board consideration. The Committee recognized that the community was calling for a solution for this possible scenario and believed that a pediatric medically urgent candidate should have the ability to be prioritized over candidates within the same classification that are not medically urgent.[50] Members initially considered creating a new classification specifically for medically urgent local pediatric candidates. Upon further discussion, the Committee thought that policy would be more consistent and inclusive if such intra-classification priority of medically urgent candidates was available within all of classifications that had a higher priority in allocation than the medical urgency classification. These classifications include inside-circle prior living donors, inside-circle pediatric candidates, and both local and national 100% highly sensitized candidates.[51] The Committee believes that because mandatory national shares for 100% highly-sensitized candidates occur in current policy, it would be consistent to apply intra-classification sorting for these candidates as well, even if it extends outside of the 250NM allocation circle.[52]

The Committee agreed that medically urgent candidates in classifications 1 through 6 in Sequence A, 1 through 6 in Sequence B, 1 through 5 in Sequence C, and 1 through 4 in Sequence D should be prioritized over non-medically urgent candidates within those classifications. As a result, the Committee felt that new sorting language was necessary to distinguish how these candidates are sorted within these classification and how it differs from how candidates are sorted within classifications with a lower priority than the medical urgency classification.

[49] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[50] April 2, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[51] April 20, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[52] *Ibid.*

Documentation and Oversight

Feedback that garnered significant consideration from the Committee following the close of the OPTN Public Comment period was the suggestion that a prospective review may be more appropriate for cases of medical urgency.[53] This policy mechanism garnered robust discussion when the Subcommittee originally developed the proposal, and that discussion was re-opened after a few committees and stakeholder organizations supported the idea of a prospective review.

The Committee considered the option carefully, and members of the Committee that serve as representatives to their regions outlined the arguments presented at their respective regional meetings.[54,55] Community concerns centered around the possibility that a retrospective review may allow for the classification to be used inappropriately and for a candidate to obtain significant allocation priority only to find out after the fact that said candidate should not have been considered medically urgent.[56] Furthermore, some community members inquired as to why a prospective review was less feasible when cases should be truly rare.[57]

The Committee believes that, based on its proposed definition of medical urgency and strict eligibility requirements, that cases will, in fact, be rare. However, because no OPTN data is currently collected on the number of transplants performed as a result of medical urgency exceptions in current policy, it is not possible to predict volume. Furthermore, since not all DSAs currently have standing policies for operationalizing medical urgency exceptions, the Committee cannot predict how many cases will be generated at the outset of the policy as a result of a new national standard for such cases being implemented. The Committee has concerns about mandating a prospective review at the outset of the policy if it cannot project case volume, especially when candidates that meet the definition of medical urgency may have a higher chance of waitlist mortality without a life-saving transplant.[58]

The higher chance of waitlist mortality for medically urgent candidates is also a primary concern of the Committee and a principal consideration towards the original proposal of a retrospective review. The Committee recognizes that a candidate that may have completely exhausted all access and may only have days to live if a life-saving transplant is not received needs to receive priority immediately, but not without some form of oversight and assurance of compliance. Similarly, the Committee believes that candidates being dialyzed through “long-shot” methods of access such as IVC catheters, based on their sound medical judgement, also need priority immediately.[59] While the Committee understands that these two types of candidates may be in different clinical situations, they believe that both conditions require immediate priority in allocation in order that lives are not lost waiting for priority approval from a prospective review board.[60]

[53] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[54] April 2, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[55] April 20, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[56] April 2, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[57] OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[58] April 20, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[59] Ibid.
[60] Ibid.

Additionally, the Committee considered other instances in policy where high allocation priority is awarded with a retrospective review as oversight mechanism. Specifically, status 1, 1A, and 1B exceptions in heart allocation via OPTN Policy 6.1.A[61] as well as status 1A and 1B exceptions in liver allocation via OPTN Policy 9.3.[62] Policy language for the latter exceptions mirrors proposed language for medical urgency priority, stating, "the Liver and Intestinal Organ Transplantation Committee will retrospectively review all exception candidates registered at status 1A or 1B and may refer these cases to the Membership and Professional Standards Committee (MPSC) for review according to Appendix L of the OPTN Bylaws."[63]

Based on this rationale, the Committee decided to proceed with a proposal including a retrospective review; however, members did feel that said review needs to be made mandatory, and not at the Committee's discretion.[64] Therefore, the original proposed language that the Committee "may" retrospectively review these cases has been amended to read that the Committee "will" review these cases. The Committee expressed interest in post-implementation evaluation and review as early as 3-months following policy implementation.[65]

Proposal for Board Consideration

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:

Candidates eligible to receive priority for medical urgency would be defined by the following 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

- Transhepatic IVC Catheter
- Translumbar IVC Catheter

[61] OPTN Policy 6.1.A, *Adult Heart Status 1 Requirements*, (April 4, 2020).
[62] OPTN Policy 9.3, *Status Exceptions*, (April 4, 2020).

[63] OPTN Policy 9.3, *Status Exceptions*, (April 4, 2020).
[64] April 2, 2020, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).
[65] *Ibid.*

- Other (must specify method)

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 according to **Figure 5** below, illustrated in red:

Figure 5: Proposed Priority of Medical Urgency Classification by Sequence (with Intra-Classification Priority Represented)

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)

The Committee proposes that medically urgent candidates in classifications 1 through 6 in Sequence A, 1 through 6 in Sequence B, 1 through 5 in Sequence C, and 1 through 4 in Sequence D would be prioritized over non-medically urgent candidates within those classifications. These classifications are indicated in green in Figure 5.

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. The only exception is for mandatory national shares that already exist in OPTN policies for 100% highly-sensitized candidates. In these cases, medically urgent 100% highly sensitized national candidates will be prioritized within their classification above non-medically urgent 100% highly sensitized national candidates.

In the rare occurrence of two medically urgent candidates appearing in the same classification 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 priority 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 be applied to KP candidates seeking an isolated kidney. However, the priority would apply only to the isolated kidney, and not both the kidney and pancreas. The candidate could be classified as medically urgent to receive the isolated kidney if 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 will conduct periodic retrospective review of medically urgent candidates. If during that review, the Committee believes that the medical urgency classification has been applied inappropriately and that further review is necessary, the Committee proposes referring the cases to the OPTN MPSC for compliance oversight.

OPTN Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[66]

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires 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:

- **Is 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. The Committee's decisions were informed primarily by their collective clinical expertise, however, the Committee also reviewed available OPTN data, literature, and practices in other countries to support their recommendations.
- **Seeks to achieve the best use of donated organs**[67] by ensuring organs are allocated and transplanted according to medical urgency. This proposal defines medically urgent and ensures that those candidates meeting the definition are prioritized for organ offers. The Committee intends for medically urgent candidates to be transplanted more quickly, thereby reducing that cohort's risk of dying on the waiting list.
- **Is designed to avoid wasting organs.**[68] It is not intended or expected to increase the number of organs recovered for transplant but not transplanted. Furthermore, by limiting priority for medically urgent candidates within the 250 NM circle alone, the Committee believes that organ wastage can be mitigated by limiting additional cold ischemic time on kidneys that are going to

[66] 42 CFR §121.4(a) (1).
[67] 42 CFR §121.8(a)(2).
[68] 42 CFR §121.8(a)(5).

be transplanted into candidates with less favorable post-transplant outcomes, based on their condition.

- **Is designed to avoid futile transplants[69]:** The Committee considered information regarding whether candidates that are medically urgent are likely to have worse post-transplant outcomes. While the Committee found that some medically urgent candidates may have a higher risk of delayed graft failure, the Committee did not determine that providing medically urgent candidates increased priority for transplant would result in poor post-transplant outcomes in the long-term.
- **Is 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. It seeks to define medical urgency, to make sure similarly situated candidates are classified similarly, and to also ensure that those medically urgent candidates have equitable access to offers by increasing their priority in the kidney allocation sequences. In order to promote patient access to transplant for other particular patient populations, such as 100% highly sensitized candidates whose "immune system makes it difficult for them to receive organs,"[70] the Committee determined that they should be prioritized prior to the medically urgent candidates.
- **Is 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 solution 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 candidate's place of listing. Candidates defined as medically urgent that are within 250NM of the donor hospital will receive offers prior to other medically urgent candidates because candidates defined as medically urgent are likely to have worse post-transplant outcomes[71] and the Committee determined that the risk of organ wastage or delayed graft function leading to futile transplants would increase if the medically urgent recipients received organs that had traveled further and thus had more cold ischemic time.[72]

This proposal also preserves the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[73] and it is specific to an organ type, in this case kidneys.[74]

The OPTN Final Rule also requires the OPTN to consider **"whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies."[75]** The Committee considered transition procedures that may be necessary to ensure that candidates that have medical urgency priority under current policy receive immediate priority if the proposed policy is implemented, assuming these candidates meet the proposed definition. As a transition procedure, the Committee recommends allowing transplant programs to enter eligibility criteria for existing medically urgent candidates into the Waitlist[SM] data collection instrument tool in the days preceding policy implementation to ensure that the day the policy becomes effective, the medically urgent candidates will receive immediate priority. In order to maintain the medical urgency priority,

[69] *Ibid.*
[70] 42 U.S.C. §274(b)(2)(A)(ii)
[71] Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at https://optn.transplant.hrsa.gov/
[72] *Ibid.*
[73] 42 CFR §121.8(a)(3)
[74] 42 CFR §121.8(a)(4)
[75] 42 CFR §121.8(d)

programs will need to enter data prior to implementation. Existing candidates with medical urgency priority must meet the proposed medical urgency definition and enter the data prior to implementation, in order to maintain their priority at time of policy implementation.

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

- **Promotes the efficient management of organ placement**[76] This proposal will not impact factors such as how OPOs recover organs, how long it might take to allocate the organs, or the resources or logistics involved in recovering, allocating, or transporting the organ from the donors to the medically urgent candidates. Furthermore, it will not affect efficiency of placement on the part of the transplant programs, as it will replace a current practice for obtaining a medical urgency exception with a new practice that is no more administratively burdensome and will not negatively affect efficiency of utilization decisions.

Alignment with OPTN Strategic Plan[77]

1. ***Improve equity in access to transplants:*** This proposal seeks to improve equity in access to transplant by providing a consistently applied and rationally determined definition for medical urgency. Prior to the OPTN Board of Directors approval of allocation policies to eliminate the use of DSA as a unit of allocation, the definition of "medical urgency" was determined at the DSA level. By providing a standardized, national definition for a condition for which a candidate may receive higher priority organ allocation, candidates' eligibility for such priority would not be determined by the DSA within which they are listed.
2. ***Improve waitlisted patient, living donor, and transplant recipient outcomes:*** By including candidates with imminent loss of dialysis access within the standardized definition of medical urgency, the proposal seeks to improve patients and transplant recipient outcomes by granting them priority in allocation before they completely loss dialysis access, when outcomes may be worsened. Specifically, this proposal seeks to reduce mortality on the waitlist by giving medically urgent candidates increased access to donated organs.

Implementation Considerations

Member and OPTN Operations

Operations affecting Histocompatibility Laboratories

The Committee does not anticipate this proposal having any implementation considerations relevant to histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

OPO staff will need to understand the implementation of this new policy and that it removes prior policy language that prescribed management of these exceptions at the DSA level. The match run will

[76] *Ibid.*
[77] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

automatically prioritize and sort medically urgent candidates into the appropriate classifications, so OPOs simply need to follow the match run.

Operations affecting Transplant Hospitals

The Committee proposes that the medical urgency classification should be applied to a candidate's listing only after new data fields on the Waitlist[SM] 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" candidate status on the waitlist form is selected. The fields require indication that the candidate 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 does anticipate minor implementation considerations for transplant hospitals. Staff training on new processes for obtaining priority for medical urgency and how new data will be represented in the Waitlist[SM] data collection instrument will be necessary. Furthermore, staff may need to enter data for any existing medically urgent candidates into the Waitlist[SM] data collection instrument tool in the days preceding policy implementation in order to ensure that current medically urgent candidates receive priority immediately under the new policy, assuming they meet the criteria of the proposed definition.

Operations affecting the OPTN

This proposal may require the submission of data that are not presently collected by the OPTN. In the retrospective review process as proposed, a candidate that meets the definition of medical urgency will receive the priority immediately when the transplant program indicates such a status in the Waitlist[SM] data collection tool. Candidates would be required to submit supporting documentation indicating a candidate's medically urgent status within seven (7) business days. The use of this status would be reviewed by the Committee retrospectively and if the Committee felt that the classification was misused, they could refer such an instance to the OPTN MPSC.

The collection of official OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB).

The OPTN will also create educational materials for the new medically urgent kidney candidate policies. Education will coincide with implementation.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility labs.

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on Organ Procurement Organizations.

Projected Impact on Transplant Hospitals

This proposal is not anticipated to have any fiscal impact on Transplant Hospitals

Projected Impact on the OPTN

A significant development effort was conducted by Policy and Community Relations, including frequent committee and subcommittee meetings, as well as additional internal team meetings to ensure alignment across IT, the Organ Center, Research, and other internal stakeholders.

A Very Large IT implementation effort, estimated at 2,070 hours, includes a four-person team over an anticipated four-month programming period. Professional Education and Communications anticipate a small effort comprising an instructional offering, system notice, targeted member email, and training.

Research and IT anticipate several hours weekly for ongoing monitoring, especially to analyze Potential Transplant Recipient (PTR) data. Member Quality anticipates 10 hours per year due to any kidney case referrals for MPSC review.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "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."[78]

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. The OPTN Kidney Transplantation Committee will review all uses of the medical urgency classification and priority status retrospectively. OPTN staff will compile medical urgency designations at a periodicity to be determined.

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?

[78] CFR §121.8(a)(7).

- What were the post-transplant outcomes of medically urgent transplant recipients?
- How long do candidates wait in medically urgent status before receiving a transplant?
- What is the waitlist mortality rate of candidates designated as medically urgent?

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:

- Number and percentage of candidates on the waiting list who received medically urgent allocation priority, overall and by candidate characteristics including:
    - Calculated panel reactive antibody score (%)
    - Expected post-transplant survival score (%)
    - Age group
    - Primary vs. repeat transplant
    - Time on dialysis
- Distribution of time in medical urgency classification before WL removal (minimum, 25th percentile, mean, standard deviation, median, 75th percentile, maximum)
- Waiting list outcomes for candidates placed in medical urgency status including:
    - Number and percentage of waiting list removals by removal reason
    - Median time to transplant calculated using the competing risks extension of Kaplan Meier survival
    - Number and percentage of deceased donor kidney transplants by kidney donor profile index 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 delayed graft function rates for medically urgent transplant recipients (compared to non-medically urgent transplants)

Conclusion

The Committee's belief that a solution to provide priority to candidates that meet their proposed definition of medical urgency language is grounded in language in the OPTN Final Rule § 121.8 (b) (2). This section states as a performance goal, "Setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent."[79]The Committee made it clear following the development of their proposal to remove DSA and region from allocation that finding a solution to ensure that these critical candidates still had an avenue to receive priority in allocation must be a priority in order to prevent increases in waitlist mortality by providing life-saving organs to candidates with the highest medical urgency.[80] The Committee's proposal seeks to provide a rationally determined and consistently applied definition for medical urgency in order that candidates with complete loss of dialysis access or 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-

[79] 42 C.F.R. § 121.4 (a) (1)
[80] October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

gathering process and deliberations was to try to mirror the current policy and practices of transplant programs within the new allocation environment, while also understanding that transitioning a policy from a DSA-based practice to a national practice would require flexibility. 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.[81] In response to community feedback received during public comment, the Committee added additional eligibility criteria to the definition of medical urgency, created intra-classification priority for medically urgent candidates in classifications with a higher priority than the medical urgency classification, and strengthened language around the Committee's retrospective review process. Committee members believe that their definition for medical urgency and proposed solution for implementation is appropriate based on these goals and principles, reflects community feedback, and is a product of sound medical judgement, evidence-gathering, and community feedback.

[81] 42 C.F.R. § 121.8.

Policy Language

Proposed new language is underlined (example) 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

8.2 Exceptions

~~8.2.A Exceptions Due to Medical Urgency~~

8.2.~~B~~A Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

8.4 Waiting Time

8.4.C Time at Medically Urgent Status

For registered kidney candidates that also qualify for medically urgent status according to Policy 8.5.A.i., the candidate accrues time at medically urgent status while active on the waiting list, based on the date the transplant program first indicates the candidate's qualification for medically urgent status to the OPTN.

8.4.~~C~~D Waiting Time for Kidney Recipients

8.5 Kidney Allocation Classifications and Rankings

8.5.A Candidate Classifications

8.5.A.i Medically Urgent Status

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 candidate's transplant surgeon and transplant nephrologist must review and sign a written approval of the candidate's qualification for medical urgency status, based on the criteria above. The transplant hospital must document this medical urgency qualification in the candidate's medical record and submit supporting documentation to the OPTN within seven business days of indicating medical urgency status.

The Kidney Transplantation Committee will review a transplant program's use of the medical urgency status retrospectively. Cases may be referred to Membership & Professional Standards Committee (MPSC) for review according to Appendix L of the OPTN Bylaws.

8.5.C Sorting Within Each Classification

For candidates within classifications 1 through 7 according to *Tables 8-6* and *8-7*; classifications 1 through 6 according to *Table 8-8*, and classifications 1 through 5 according to *Table 8-9*, candidates are sorted in the following order:

1. Medical urgency status
2. Total time at medically urgent status for current medically urgent candidates only (highest to lowest)
3. Total points (highest to lowest)
4. Date and time of the candidate's registration (oldest to most recent)

For candidates within all other classifications, ~~within each classification~~, candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

8.5.F Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in classifications 1 through ~~8~~ 4, 8 or 9 according to *Table 8-6* and *8-7*; classifications 1 through ~~7~~ 4, 7 or 8 according to *Table 8-8*; and classifications 1 through ~~6~~ 4, 6 or 7 in *Table 8-9*, the transplant program's HLA laboratory director and the candidate's transplant physician or surgeon must review and sign a written approval of the unacceptable antigens listed for the candidate. The transplant hospital must document this approval in the candidate's medical record.

8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-6* below.

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
7	Medically Urgent	250NM	Any
8	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	CPRA equal to 99%, blood type identical or permissible	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:
10	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
12	0-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
13	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
14	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
15	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
16	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
17	0-ABDR mismatch, top 20% EPTS, and blood type B	250NM	O
18	0-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	O

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:
19	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	O
20	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	O
21	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
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
24	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
25	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
26	0-ABDR mismatch, top 20% EPTS, 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:
27	Top 20% EPTS, blood type B	250NM	A2 or A2B
28	Top 20% EPTS, blood type permissible or identical	250NM	Any
29	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
30	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
31	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
32	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	O
33	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	O
34	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
35	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	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:
36	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
37	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
38	EPTS greater than 20%, blood type B	250NM	A2 or A2B
39	All remaining candidates, blood type permissible or identical	250NM	Any
40	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
41	Top 20% EPTS, blood type B	Nation	A2 or A2B
42	Top 20% EPTS, blood type permissible or identical	Nation	Any
43	All remaining candidates, blood type permissible or identical	Nation	Any

8.5.I 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.

Table 8-7: Allocation of Kidneys from Deceased Donors with 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:
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
7	Medically Urgent	250NM	Any
8	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	CPRA equal to 99%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, CPRA equal to 98%, 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:
11	CPRA equal to 98%, blood type permissible or identical	250NM	Any
12	0-ABDR mismatch, blood type identical	250NM	Any
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
14	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
15	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
16	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
17	0-ABDR mismatch, blood type B	250NM	O
18	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
19	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 B	Nation	O

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:
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	O
21	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
22	0-ABDR mismatch, blood type permissible	250NM	Any
23	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
24	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
25	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
26	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
27	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

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:
28	Blood type B	250NM	A2 or A2B
29	All remaining candidates, blood type permissible or identical	250NM	Any
30	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
31	Blood type B	Nation	A2 or A2B
32	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 ~~29~~ 30 for one deceased donor kidney
- Classifications ~~30 and 31~~ 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

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:
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	Medically Urgent	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	CPRA equal to 98%, blood type permissible or identical	250NM	Any
11	0-ABDR mismatch, blood type identical	250NM	Any
12	0-ABDR mismatch, CPRA greater than or equal to 80%, 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:
13	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
14	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
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, and blood type B	250NM	O
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	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 B	Nation	O
19	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	O
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
21	0-ABDR mismatch, blood type permissible	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:
22	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	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
24	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
25	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	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
27	Blood type B	250NM	A2 or A2B
28	All remaining candidates, blood type permissible or identical	250NM	Any
29	Blood type B	Nation	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:
30	All remaining candidates, blood type permissible or identical	Nation	Any
31	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
32	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 ~~20, 22, and 23~~ 21, 23 and 24 for one deceased donor kidney
- Classifications ~~21 and 24~~ 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

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:
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	Medically Urgent	250NM	Any
6	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
9	CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, blood type permissible or identical	250NM	Any
11	0-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
13	0-ABDR mismatch, blood type B	250NM	O

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:
14	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
16	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
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
19	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
20	Blood type B	250NM	A2 or A2B
21	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

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:
23	Blood type B	Nation	A2 or A2B
24	All remaining candidates, blood type permissible or identical	Nation	Any
25	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

8.7.A Choice of Right versus Left Donor Kidney

If both kidneys from a deceased donor are able to be transplanted, the transplant hospital that received the offer for the candidate with higher priority on the waiting list will get to choose first which of the two kidneys it will receive.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% (classifications 1 through ~~8~~ 4, 8 or 9 *in Tables 8-*6 *and 8-7*; classifications 1 through ~~7~~ 4, 7 or 8 *in Table 8-8*; and classifications 1 through ~~6~~ 4, 6 or 7 *in Table 8-9*) or to a combined kidney and non-renal organ candidate, the host OPO determines whether to offer the left or the right kidney.

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