

Notice of OPTN Policy Change

Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations

Sponsoring Committees:	Minority Affairs and Kidney Transplantation
Policy Affected:	<p><i>1.2: Definitions</i></p> <p><i>3.6.B.i: Non- function of a Transplanted Kidney</i></p> <p><i>8.4.A: Waiting Time for Candidates Registered at Age 18 Years or Older</i></p> <p><i>8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i></p> <p><i>9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions</i></p> <p><i>9.9.B: Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older</i></p> <p><i>13.7.G: OPTN KPD Waiting Time Reinstatement</i></p>
Public Comment:	January 27, 2022 – March 23, 2022
Board Approved:	June 27, 2022
Effective Date:	July 27, 2022

Purpose of Policy Change

Current OPTN policy is not prescriptive as to what methods of GFR measurement or estimation programs should or should not be used when registering kidney candidates.¹ There are several widely used estimated GFR (eGFR) formulas with varying compositions that sometimes include a Black race coefficient. Because current OPTN policy is not prescriptive, equations that include and exclude the race coefficient are currently permitted for OPTN use. Overestimated eGFR values resulting from race adjustments have the potential to delay referral for kidney transplantation and the initiation of qualifying waiting time.² Research has shown that the use of race adjustments in the calculation of eGFR has the potential to exacerbate existing disparities and negatively impact patient outcomes.³ This proposal defines GFR within *OPTN Policy 1.2: Definitions* so that any eGFR calculation used must not contain a race-based coefficient. This requirement for race-neutral calculations intends to more accurately estimate Black kidney candidates' GFR values.

¹ OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

² Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. *American Medical Association*. 2019. 322(2):113-114.

³ Reese PP, Sumit M, King KL, Williams WW, Potluri VS, Harhay MN, Eneanya ND. Racial disparities in preemptive waitlisting and deceased donor kidney transplantation: Ethics and solutions. *The American Journal of Transplant*. 2020. 21:958–967. <https://doi.org/10.1111/ajt.16392>.

Proposal History

In August 2021, the Minority Affairs and Kidney Transplantation Committees released the *Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation Request for Feedback (RFF)* to solicit community input on potential changes to OPTN policy to restrict the use of the Black race coefficient in eGFR calculations.⁴ The vast majority of feedback was supportive of establishing an OPTN requirement for race-neutral eGFR calculations.⁵ This feedback was used to develop the proposal to prohibit race-inclusive eGFR calculations for the winter 2022 public comment period, which also received widespread support from the community.

Summary of Changes

Define GFR in OPTN Policy 1.2: Definitions: *A measure of filtering capacity of the kidneys. GFR can be measured directly or estimated (eGFR) using various formulae. Formulae used to calculate an eGFR must not use a race-based variable.*

Impact on waiting time and prioritization policies: Require that race-neutral eGFR calculations are used for the following OPTN policies regarding waiting time and prioritization

- *3.6.B.i: Non-function of a Transplanted Kidney*
- *8.4.A: Waiting Time for Candidates Registered at Age 18 Years or Older*
- *8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*
- *9.9.B: Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older*
- *13.7.G: OPTN KPD Waiting Time Reinstatement*

Impact on OPTN Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions: Requirement for a race-neutral eGFR calculation. Current policy requires use of the MDRD6 eGFR calculation, which includes a race-based variable.

Implementation

Upon implementation on July 27, 2022, transplant hospitals will not be permitted to use eGFR calculations that include race for purposes of the OPTN. Transplant hospitals that have not already transitioned to the use of race-neutral eGFR calculations will need to do so before this time. The transition process could include program-wide notification of this policy change and training for staff. Transplant hospitals may also have to update their electronic medical records and work with lab partners to modify eGFR calculation and reporting for purposes of the OPTN.

The OPTN will implement the proposed changes to policy in the OPTN Computer System. There will be limited changes to the OPTN Waiting List system, including modifications to data field labels on the kidney and kidney-pancreas candidate records as well as the simultaneous liver-kidney section of the liver candidate record. Additionally, appropriate modifications will be made to update MELD/PELD Exception forms with GFR references.

⁴ OPTN, Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations, https://optn.transplant.hrsa.gov/media/f2qpjia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed July 16, 2022)

⁵Ibid.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~)

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

Glomerular Filtration Rate (GFR)

A measure of filtering capacity of the kidneys. GFR can be measured directly or estimated (eGFR) using various formulae. Formulae used to calculate an eGFR must not use a race-based variable.

3.6.B.i Non-function of a Transplanted Kidney

Immediate and permanent non-function of a transplanted kidney is defined as *either*:

- Kidney graft removal within the first 90 days of transplant documented by an operative report of the removal of the transplanted kidney.
- Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) or ~~calculated glomerular filtration rate (GFR)~~ less than or equal to 20 mL/min within 90 days after the candidate's kidney transplant.

Kidney waiting time will be reinstated when the OPTN receives a completed *Renal Waiting Time Reinstatement Form* and the supporting documentation required above. The Estimated Post Transplant Survival (EPTS) score will also be calculated without interruption. The OPTN will send a notice of waiting time reinstatement to the transplant hospital involved.

8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older

If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following:

1. The candidate's registration date with a glomerular filtration rate (GFR) or measured or ~~calculated-estimated~~ creatinine clearance (CrCl) or ~~glomerular filtration rate (GFR)~~ less than or equal to 20 mL/min.
2. The date after registration that a candidate's GFR or measured or ~~calculated-estimated~~ creatinine clearance CrCl or GFR becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

8.5.G Prioritization for Liver Recipients on the Kidney Waiting List

If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the same deceased donor, the candidate will be classified as a prior liver recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date

40 2. On a date that is at least 60 days but not more than 365 days after the candidate's liver
41 transplant date, at least *one* of the following criteria is met:

- 42 • The candidate has a GFR or measured or ~~calculated~~ estimated creatinine clearance
43 (CrCl) or ~~glomerular filtration rate (GFR)~~ less than or equal to 20 mL/min.
- 44 • The candidate is on dialysis.

45
46 When the transplant program reports that the candidate meets the criteria for this
47 classification, the candidate will remain at this classification for 30 days from the date of the
48 qualifying test or treatment. If the transplant program reports additional qualifying tests or
49 treatments, then the candidate will remain at this classification for 30 days from the most
50 recent date of the test or treatment. If the transplant program reports that the candidate meets
51 the criteria for 90 consecutive days, the candidate will remain at this classification until the
52 candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time
53 according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90
54 consecutive days, then the candidate's classification will be included in the transfer.

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56 If a liver recipient receives a kidney using this priority classification and returns to the kidney
57 waiting list after the most recent kidney transplant, the candidate must again meet the criteria
58 for this classification, unless the candidate qualifies for kidney waiting time reinstatement
59 according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*. If the candidate qualifies for
60 kidney waiting time reinstatement, the candidate will be classified as qualifying for the
61 classification.

62
63 If a kidney candidate received a liver and kidney transplant from the same deceased donor, the
64 candidate will only qualify for this classification if the candidate qualifies for kidney waiting time
65 reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*

66 67 **9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions**

68 A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the
69 candidate's transplant hospital submits evidence of all of the following:

- 70 1. The liver candidate is registered on the waiting list for a kidney transplant at that transplant
71 hospital.
- 72 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample
73 analysis or genetic analysis.
- 74 3. ~~Estimated~~ Glomerular filtration rate (GFR) ~~by six variable Modification of Diet in Renal~~
75 ~~Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or~~
76 ~~iohexol,~~ is less than or equal to 25 mL/min on 2 occasions at least 42 days apart.

77 78 79 **9.9.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older**

80 Candidates who are 18 years or older when registered on the liver waiting list are
81 eligible to receive both a liver and a kidney from the same deceased donor when the

82 candidate is registered on the waiting list for both organs and meets at least *one* of the
 83 criteria according to *Table 9-17*.

84
 85 **Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation**

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Chronic kidney disease (CKD) with a measured or calculated estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days	At least <i>one</i> of the following: <ul style="list-style-type: none"> ● That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. ● At the time of registration on the kidney waiting list, that the candidate's most recent <u>GFR or measured or calculated-estimated creatinine clearance (CrCl) or GFR</u> is less than or equal to 30 mL/min. ● On a date after registration on the kidney waiting list, that the candidate's <u>GFR or measured or calculated-estimated CrCl or GFR</u> is less than or equal to 30 mL/min.
Sustained acute kidney injury	At least <i>one</i> of the following, or a combination of <i>both</i> of the following, for the last 6 weeks: <ul style="list-style-type: none"> ● That the candidate has been on dialysis at least once every 7 days. ● That the candidate has a <u>GFR or measured or calculated-estimated CrCl or GFR</u> less than or equal to 25 mL/min at least once every 7 days. If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor.
Metabolic disease	A diagnosis of at least <i>one</i> of the following: <ul style="list-style-type: none"> ● Hyperoxaluria ● Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I ● Familial non-neuropathic systemic amyloidosis ● Methylmalonic aciduria

86 **13.7.G OPTN KPD Waiting Time Reinstatement**

87 KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in
 88 the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is

89 registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active
90 and inactive status in the OPTN KPD program.

91 The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if
92 the OPTN KPD candidate experiences immediate and permanent non-function of any
93 transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program with
94 another living donor. Immediate and permanent non-function of a transplanted kidney is
95 defined as *either*:

- 96 1. Kidney graft removal within the first 90 days of transplant documented by a report of the
97 removal of the transplanted kidney.
- 98 2. Kidney graft failure within the first 90 days of transplant with documentation that the
99 candidate is either on dialysis or has a glomerular filtration rate (GFR) or measured or
100 estimated creatinine clearance (CrCl) ~~or calculated glomerular filtration rate (GFR)~~ less than
101 or equal to 20 mL/min within 90 days of the kidney transplant.

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