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For professionals: FAQs about eGFR waiting time modifications

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Important!

This page was last updated on 10/11/2023 with information on what all kidney programs are required to do after 1/3/2024. Read more details.

An Organ Procurement and Transplantation Network (OPTN) policy action is now in effect that requires transplant programs to assess their waiting lists and submit waiting time modifications for adult and pediatric Black or African American candidates affected by race-inclusive eGFR calculations.

Programs must complete the process and provide the necessary documentation to the OPTN by Jan. 3, 2024.

Read <u>the policy notice</u> (PDF) for *OPTN Policy 3.7.D Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations*.

Resources for professionals

Resources are now available to help kidney programs comply with this policy action.

- Review policy change impacts, understand policy process needs, and get sample notification and attestation language in an educational offering in the OPTN Learning Management System, known as <u>UNOS Connect</u>
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations
- Access a custom reporting tool in the OPTN Computer System (also known as UNetSM) Data Services Portal
 - The OPTN Data File "Current Waitlisted African American Candidates" provides a list of current kidney candidates reported with African American/Black as a Race category with wait time qualifying information
- Watch a <u>recording of a webinar</u> with education on the notification and modification process, hosted by OPTN Kidney Transplantation Committee Chair Martha Pavlakis, M.D.

I work at a transplant program. What will my program be required to do?

In alignment with the OPTN Final Rule, it is a priority of the OPTN to <u>provide equity in access</u> to transplantation. To do this, the OPTN board has approved a rapid implementation of eGFR waiting time modifications. This policy action involves multiple steps. It's important for transplant programs to understand the full scope so that their affected patients can benefit from updated waiting times as soon as possible.

By Jan. 3, 2024, all kidney transplant programs will be required to:

- 1. Assess their waiting list for all registered adult and pediatric Black/African American kidney candidates that have been affected by the use of race-inclusive eGFR calculations
- 2. Submit complete eGFR waiting time modifications for affected adult and pediatric candidates to the OPTN
- 3. Notify **all** registered adult and pediatric kidney transplant candidates, at two points in time:
 - a. Before the assessment of your waiting list, for awareness
 - b. After the assessment of your waiting list, to notify candidates of eligibility status
- 4. Submit attestation documentation to the OPTN confirming your program has:

a. Assessed your waiting list, submitted modifications and supporting documentation, and notified candidates

After Jan. 3, 2024, all kidney transplant programs will be required to:

- 1. Continue to notify **all** newly registered kidney candidates of the requirements of the transplant program according to the policy
- 2. Assess newly registered kidney candidates to determine eligibility
- 3. Submit completed waiting time modification requests to the OPTN for every candidate who should have qualified to accrue waiting time sooner

How should my transplant program prepare for this change?

- Transplant programs should review the policy language, policy notice, and complete the educational offering in the OPTN Learning Management System (also known as <u>UNOS Connect</u>).
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations
- Transplant programs should take the time to assess their workflows and make any staffing adjustments necessary to comply with the policy within the required timeframe.

Assessing waiting lists

Which kidney candidates are eligible for an eGFR Waiting Time Modification?

Qualifying kidney candidates must meet all the following criteria to be considered eligible:

- They are registered as Black or African American in the OPTN Computer System
- They previously had their eGFR value calculated with a race-inclusive formula
- They are accruing waiting time with eGFR, CrCl, or dialysis criteria (See *OPTN Policy 8.3.A*)

 OR are registered without qualifying criteria (see next question for details)
- The transplant program can provide documentation demonstrating that with a race-inclusive calculation, the candidate's eGFR was over 20 mL/min, but with a race-neutral calculation it would have been 20 mL/min or less

Transplant programs may submit waiting time modifications for candidates who were unable to begin accruing waiting time according to *OPTN Policy 8.3.A:* Waiting Time for Candidates Registered at Age 18 Years or Older at an earlier date due to the use of an eGFR calculation that included a race variable.

My program has candidates registered who are not yet accruing waiting time with the criteria detailed in OPTN Policy 8.3.A. Are they eligible for waiting time modifications?

Yes, these candidates are considered eligible if:

• Their eGFR value was above 20 when calculated with a race-inclusive eGFR calculation, but upon recalculation with a race-neutral eGFR calculation is 20 mL/min or less.

Are candidates registered to the OPTN waiting list between Jan. 5, 2023 and Jan. 3, 2024 eligible?

• This policy requires programs to assess candidates who were listed in this timeframe. Programs may continue to assess and submit modifications for eligible candidates registered after Jan.3, 2024.

Why are candidates qualifying with dialysis criteria included within the scope of eligibility?

• Whether or not dialysis candidate should be included in the scope of eligibility was discussed at length by the Sponsoring Committees

- The Sponsoring Committees determined that that Black or African- American candidates on dialysis should be included because these candidates can also be affected by race-inclusive eGFR calculations.
- The majority of the transplant community agreed with this more inclusive path towards equity for a population of candidates who have been historically disadvantaged.

Why are pediatric candidates included in the scope of eligibility?

- While pediatric candidates are typically assessed with different protocols, the OPTN does not know that there are zero pediatric candidates affected by race-inclusive eGFR calculations.
- The Sponsoring Committees leaned on the concept of transparency, therefore the requirements of the policy apply to all kidney candidates regardless of age.

Are candidates that are not registered as Black or African American eligible?

• Candidates who are not registered as Black or African American will not be eligible for an eGFR waiting time modification, as these candidates did not have a race-inclusive calculation used to calculate their eGFR value.

Some candidates are registered on the waiting list with multiple races. Are these candidates eligible for an eGFR waiting time modification?

- If a candidate is registered to the waiting list with multiple races and one of those races is Black or African American, it is possible that a calculation that included a race factor was used to calculate their eGFR. Programs can find more details on how to identify their Black or African American candidates in the educational offering in the OPTN Learning Management System (also known as UNOS Connect).
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

Are candidates registered for a kidney-pancreas or multi-organ transplant included in the scope of eligibility?

• This policy is limited to kidney candidates and kidney programs. Candidates registered for a kidney-pancreas or multiple organ transplant are in the scope of eligibility if they are registered for an isolated kidney.

If candidates are multi-listed, is each program required to assess these candidates and submit eGFR wait time modifications?

• Yes. Each program will be required to assess their kidney waiting list and submit modifications for all their eligible candidates regardless of whether their candidates are also listed at additional programs.

Can the OPTN help transplant programs identify which kidney candidates will qualify for a modification?

The OPTN does not collect data on what eGFR calculation was used to accrue waiting time and therefore does not have information on which of the equations were race- inclusive vs. race-neutral.

- The OPTN Data File "Current Waitlisted African American Candidates" is available in the OPTN Computer System Data Services Portal.
 - This custom report provides a list of current kidney candidates reported with African American/Black as a Race category with wait time qualifying information

- The report is a snapshot of your program's waiting list at the time it is run. The report will be updated on a weekly basis.
- An educational offering in the OPTN Learning Management System (also known as UNOS Connect) has more information.
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

Candidate notifications

What notifications are programs required to send before they assess their lists?

- Before they assess their lists, programs must inform **all** adult and pediatric kidney candidates of the requirements of the program according to the policy.
- This is the first of two required notifications.
- An educational offering in the OPTN Learning Management System (known as UNOS Connect) has more information.
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

What notifications are programs required to send after they assess their lists?

- Programs must inform all adult and pediatric kidney candidates of the completion of list assessment and of their eligibility status.
- This is the second of two required notifications.
- An educational offering in the OPTN Learning Management System (also known as UNOS Connect) has more information.
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

Which candidates must be notified?

 All kidney candidates registered at the program, regardless of race, including active and inactive adult and pediatric candidates.

Why are transplant programs required to notify all kidney candidates of the policy and their eligibility?

- Patients are at the heart of the system. The OPTN places great importance upon transparency with the entire community, especially patients.
- The OPTN must develop equitable allocation policies. With the identification of this inequitable set of calculations, the OPTN was required to act.
- The OPTN also wants to ensure that every candidate is registered with their correct race in the OPTN Computer System. Sending notifications to all candidates will be informative in the event a kidney candidate's race has been misrepresented in the OPTN Computer System.

What should a transplant program do if a kidney candidate's race has been misrepresented in the OPTN Computer System? Could this candidate qualify for an eGFR waiting time modification?

- The transplant hospital should correct this candidate's race in the OPTN Computer system.
- If the candidate's race is now Black or African-American, they must be assessed for a waiting time modification.
 - Eligibility will be determined by past use of a race-inclusive eGFR and supporting documentation outlined in the policy. If a race-inclusive eGFR calculation was never used, the candidate will not qualify.

Does this policy require notifications to be sent to those candidates who registered during the eGFR waiting time modification submission timeframe?

• Yes. This policy's candidate notification requirements apply to all kidney candidates, including those registered between Jan. 5, 2023 and Jan. 3, 2024.

Does the policy specify how a candidate should be contacted?

- No. This policy does not specify how a candidate should be contacted. The notifications may be sent as a physical letter. They can also be through other means such as email or through the electronic medical record (EMR).
 - Not all candidates maintain a permanent address, so programs should consider alternative methods of contacting candidates.
- The OPTN encourages transplant programs to retain their own documentation regarding candidate notification.

What resources can the OPTN provide to assist programs with the candidate notification piece of the policy requirement?

- The OPTN provides candidate notification samples in OPTN Learning Management System (known as UNOS Connect).
- The OPTN encourages transplant programs to retain their own documentation regarding candidate notification.
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations
 - Sample notifications were requested by the community, but the policy does not require transplant programs to use them.
 - Sample notifications can be customized to meet the needs of the candidates registered at your program.

Are the candidate notification samples available in any other language?

• Currently candidate notification samples are available in Spanish

Supporting documentation

What must supporting documentation show?

- Supporting documentation must demonstrate that with a race-inclusive calculation, the candidate's eGFR value was over 20 mL/min, but with a race-neutral calculation would have been 20 mL/min or less.
- This criteria for eligibility was established to directly link the use of a race-inclusive eGFR calculation to a candidate's
 late access to the waiting list. A candidate of any race could experience late access to the waiting list due to late
 referral, so this requirement aims to focus specifically on those disadvantaged by the use of a race-based eGFR
 calculation.

What supporting documentation must be submitted to the OPTN as part of a complete eGFR waiting time modification request?

Programs may provide documentation aligning with one of the following options:

- 1. Documentation of the candidate's eGFR value for Black and non-Black candidates: This documentation is reliable and widely available from labs, such as Quest Diagnostics or LabCorp.
- 2. Documentation showing both the estimation of GFR with a race-inclusive calculation and a re-estimation of GFR with race-neutral calculation: Not every transplant program will have access to the documentation referenced in option 1.

Programs without access to larger labs may provide the following two documents to support eGFR waiting time modifications:

- a. A lab report showing estimation of a candidate's GFR with a race-inclusive calculation, including the date and time of estimation.
- b. Evidence of re-estimation of the candidate's GFR with any race-neutral eGFR calculation demonstrating a qualifying value.

If utilizing documentation option 2: Do transplant programs need to use any specific formula to calculate eGFR?

• Any race-neutral eGFR calculation can be used. This is in alignment with the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* proposal.

What level of effort is expected of programs to acquire prior documentation for affected candidates?

- Transplant programs are expected to take the necessary steps to modify waiting times for kidney candidates disadvantaged by the use of a race-inclusive eGFR calculation. To do this, programs are expected to seek documentation by:
 - 1. Reviewing their own records
 - 2. Contacting referring nephrologists for additional information
 - 3. Contacting candidates, who may have additional information

What date range should programs assess when seeking supporting documentation?

- Candidates qualifying by dialysis: a time earlier than their dialysis start date
- Candidates qualifying by eGFR: a time earlier than their current wait time start date

How will programs know if an eGFR calculation is race-neutral?

- Calculations that have been refit without a race variable, such as the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2021 are race-neutral.
 - An example is included in an educational offering in the OPTN Learning Management System (also known as UNOS Connect).
 - KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations
- Any program can make a candidate's eGFR value race- neutral by excluding the race-based variable from the calculation.
 - For example, a program can make the MDRD (Modification of Diet in Renal Disease) 4-variable GFR Equation
 race-neutral by selecting "no" or "non-Black" when responding the "Black Race" prompt on the calculator. If "no"
 or "non-Black" is selected, the race variable will not be used to calculate the candidate's eGFR value and the
 eGFR will be reflective of a race-neutral value.

How do programs submit eGFR Waiting Time Modifications to the OPTN?

- Transplant programs are required to submit eGFR Waiting Time Modification forms to the OPTN by fax or secure email. This form is available in the OPTN Computer System on the Forms/Tools page, accessible through the Resources tab.
- Transplant programs are required to submit a form for each affected candidate, along with supporting documentation.
- An educational offering in the OPTN Learning Management System (also known as UNOS Connect) has more information.

• KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

This policy requires all programs to comply by Jan. 3, 2024. What happens if an affected candidate provides the supporting documentation after that date?

- All affected candidates may provide their transplant program with supporting documentation at any time and are not limited by the January 3, 2024 timeframe
- This timeframe was established for programs to complete the review, submit modifications, send candidate notifications, and submit attestation documentation per OPTN policy

Attestation to the OPTN

What information is required when submitting attestation documentation to the OPTN?

- Documentation attesting to both of the following:
 - 1. Notification to all candidates registered at the transplant program of their eligibility for a waiting time modification according to this policy and
 - 2. Submission of eGFR waiting time modifications for all eligible candidates registered at the transplant program

What resources will the OPTN provide to assist programs in complying with this attestation piece of the policy requirement?

- The OPTN provides attestation sample language in OPTN Learning Management System (known as UNOS Connect).
 - KID118 Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

Additional questions

Are transplant programs who have recently reviewed their list required to fulfill policy requirements?

- Yes. All kidney transplant programs are required to comply with no exceptions.
- Candidates registered until Jan. 3, 2024 must be assessed for eligibility.
- All programs are required to comply with all parts of policy 3.7.D, including the requirement for two candidate notifications.
 - The purpose of the first notification is to give kidney candidates the opportunity to bring forward any supporting documentation that is not within the transplant program's system
 - During the development of this policy, the sponsoring committees felt strongly that kidney candidates should be given this opportunity to self- advocate

Are transplant programs that have been using race- neutral eGFR calculations for years required to fulfill policy requirements?

- Yes. All kidney transplant programs are required to comply with no exceptions.
- Candidates registered until Jan. 3, 2024 must be assessed for eligibility.
- All programs are required to comply with all parts of policy 3.7.D, including the requirement for two candidate notifications.
 - The purpose of the first notification is to give kidney candidates the opportunity to bring forward any supporting documentation that is not within the transplant program's system

be given this opportunity to self- advocate