Notice of OPTN Policy Change

Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations

Sponsoring Committees: **Minority Affairs and Kidney Transplantation**
Policy Affected: *3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations*

Public Comment: **August 3, 2022-September 28, 2022**
Board Approved: **December 5, 2022**
Effective Date: **January 5, 2023**

Purpose of Policy Change

The inclusion of the race variable in eGFR calculations has shown to increase eGFR values by as much as 16% for Black or African-American individuals. Overestimated eGFR values resulting from race adjustments have the potential to delay referral for kidney transplantation and the initiation of qualifying waiting time.[1] This policy provides a pathway for Black or African-American kidney candidates who have been affected by race-inclusive eGFR calculations to obtain waiting time they would have otherwise earned had a race-neutral eGFR calculation been used.

Proposal History

When the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* policy was implemented in July 2022, requirements for eGFR race-neutrality were applied prospectively.[2] This means that after the policy's implementation date, transplant programs were required to use race-neutral eGFR calculations for all purposes of the OPTN, including initiation of waiting time accrual for kidney transplantation candidates. This policy addresses waiting time modifications for registered candidates that have been disadvantaged by the use of a race-inclusive eGFR calculation.

Summary of Changes

*OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculation*s:

- Mandates transplant programs submit complete eGFR waiting time modifications for all affected candidates
- Establishes that eligible candidates include both dialysis and pre –dialysis candidates, and that documentation must support that an earlier, race-inclusive eGFR value was above 20 mL/min, but if a race-neutral eGFR calculation was used, the eGFR would have been 20 mL/min or less

---

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

[2] OPTN Public Comment. Establish OPTN Requirement for Race- Neutral eGFR Calculations, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022 https://optn.transplant.hrsa.gov/media/f2qpujia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed June 9, 2022)

- Requires transplant programs to notify all registered kidney candidates at two points in time: 1) before program assessment of waiting list for awareness and 2) after program assessment of waiting list to inform candidates of their eligibility
- Requires programs to submit documentation to the OPTN attesting to the completion of their kidney waiting list review, submission of complete modifications for all eligible kidney candidates, and notification to all kidney candidates by the end of the timeframe

Implementation

On or before January 3, 2024, transplant programs are responsible for:
- Assessment of their kidney transplant waiting lists
- Submission of complete requests for waiting time modifications
- Completion of candidate notification requirements
- Submission of attestation documentation to the OPTN

This policy change will not require action from Organ Procurement Organizations (OPOs) or histocompatibility laboratories.

The OPTN is responsible for communications to members, system notices, training/education, monitoring process updates, and Organ Center review of submitted modifications.

Affected Policy Language

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

3.7.D Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

3.7.D.i   Notification Requirement

All designated kidney transplant programs must notify every candidate registered at the transplant program of the responsibilities of the program pursuant to *Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations.*

3.7.D.ii   Determination of Eligible Candidates

All designated kidney transplant programs must determine eligibility for a Waiting Time Modification for Kidney Candidates affected by Race-Inclusive eGFR Calculations for each candidate registered at the transplant program. A candidate is eligible for a waiting time modification if the candidate is registered as Black or African-American in the OPTN Computer system and has documentation establishing that the candidate had an eGFR that was over 20 mL/min and would have been 20 mL/min or less if a race-neutral calculation had been used.

3.7.D.iii   Application for Waiting Time Modification

Transplant programs must submit an eGFR waiting time modification for each eligible candidate registered at their transplant program. The application for an eGFR waiting time modification must include the qualifying eGFR value, as well as:

1. Documentation of one of the following:
- The candidate's eGFR values for Black and non-Black candidates or
- The estimation of GFR with a race-inclusive calculation and a re-estimation of GFR with a race-neutral calculation
2. The name and signature of the candidate's physician or surgeon.

Upon receipt of a complete application the OPTN will implement the waiting time modification.

3.7.D.iv   Reporting Requirements for Kidney Transplant Programs

All designated kidney transplant programs must submit an attestation to the OPTN by January 3, 2024, signed by the transplant program director (or their designee), affirming that the program has completed both of the following:

- Notification to all candidates registered at the transplant program of their eligibility for a waiting time modification according to this policy and
- Submission of eGFR waiting time modifications for all eligible candidates registered at the transplant program.