

Notice of OPTN Living Donor Exclusion Criteria Changes

Modify Living Donor Exclusion Criteria

Sponsoring Committee:	OPTN Living Donor Committee
Policy Affected	OPTN Policy 14.4.E: Living Donor Exclusion Criteria
Public Comment:	January 27, 2022 – March 23, 2022
Board Approved:	June 27, 2022
Effective Date:	July 26, 2022

Purpose of Policy Changes

The Committee's review of OPTN Policy 14.4.E: *Living Donor Exclusion Criteria* ensures the relevancy of living donor exclusion criteria from a perspective of maintaining living donor and transplant recipient safety. The Committee's review led to proposed modifications supported by current research, which may broaden individuals' opportunities to become living organ donors. OPTN Policy 14.4.E was holistically reviewed and assessed for relevancy as the living donor exclusion criteria have not been evaluated since its implementation in 2014. The Committee strives to protect the safety of living donors and transplant recipients, while also ensuring living donation barriers are limited.

Proposal History

- February 2021 – April 2021: The Committee sponsored a workgroup to analyze the problem and the literature
- May 2021 – November 2021: The Committee reviewed the fourteen living donor exclusion criteria in OPTN policy
- January 2022 – March 2022: Proposal submitted for public comment
- April 2022: The Committee reviewed public comment feedback, made post-public comment changes, and voted to send the proposal to the OPTN Board of Directors
- June 27, 2022: OPTN Board of Directors approved the proposed modifications to living donor exclusion criteria in OPTN policy

Summary of Changes

Four living donor exclusion criteria in OPTN policy will be affected. Two living donor exclusion criteria are modified to align language within other sections of OPTN living donor policy. The third modification relates to the malignancy exclusion criterion for all living organ donors. This modification intends to exclude individuals with malignancies that require treatment, other than surveillance, or have a more than known minimal risk of transmission. The final modification addresses the diabetes exclusion criterion for living kidney donors. The modification maintains type 1 diabetes as an absolute contraindication to living kidney donations, while excluding individuals with type 2 diabetes that have evidence of end organ damage or an unacceptable lifetime risk of complications.

Implementation

All transplant programs that perform living donor evaluations will need to become familiar with the modifications to living donor exclusion criteria, especially the new language surrounding malignancy and diabetes. This proposal does not require transplant programs to change their living donor evaluation and acceptance practices. However, should a transplant program choose to expand their living donor evaluation and acceptance practices based on the modifications, there may be additional administrative burden for programs to adapt evaluation protocols. These modifications are not anticipated to affect the operations of histocompatibility laboratories or organ procurement organizations.

The changes to OPTN living donor policy language will not require information technology (IT) effort, and no member actions are required. Communications and education will be developed and deployed across appropriate channels to inform members.

The Committee will receive monitoring reports using pre- versus post-implementation comparisons after approximately 6 months, 1 year, and 2 years.

Affected Policy Language

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

14.4.E Living Donor Exclusion Criteria

Table 14-10: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	<p>Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</p> <p>Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:</p> <ul style="list-style-type: none"> • Is both less than 18 years old and mentally incapable of making an informed decision • HIV, unless the requirements for a variance are met, according to <i>Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors</i> • Active malignancy, or incompletely treated malignancy <u>that either</u> <ul style="list-style-type: none"> ○ <u>requires treatment other than surveillance or</u> ○ <u>has more than minimal known risk of transmission</u> • High suspicion of donor <u>inducement, coercion, or other undue pressure</u> • High suspicion of <u>knowingly and unlawfully acquiring, receiving, or otherwise transferring anything of value in illegal financial exchange for any human organ between donor and recipient</u> • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
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<p style="text-align: center;">Additional Exclusion Criteria for Living Kidney Donors</p>	<p>Kidney recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</p> <ul style="list-style-type: none"> • Uncontrollable hypertension or history of hypertension with evidence of end organ damage • Diabetes • <u>Type 1 diabetes</u> • <u>Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals either</u> <ul style="list-style-type: none"> ○ <u>evidence of end organ damage or</u> ○ <u>unacceptable lifetime risk of complications</u>
<p style="text-align: center;">Additional Exclusion Criteria for Living Liver Donors</p>	<p>Liver recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</p> <ul style="list-style-type: none"> • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor