OPTN

Mini-Brief

Align Units of Distribution in Closed Variance for Split Liver Transplantation

OPTN Liver and Intestinal Transplantation Committee

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Align Units of Distribution in Closed Variance for Split Liver Transplantation

Affected Policies: Sponsoring Committee: Public Comment Date: 9.11.C Closed Variance for Any Segment Liver Transplantation Liver and Intestinal Transplantation October 15 - November 14, 2019

Executive Summary

The OPTN Board of Directors (the Board) approved a new closed variance for the allocation of the second segment of split livers on June 10, 2019.¹ The variance permits participating transplant programs to offer the second segment of the split liver to a candidate at the same transplant program or an affiliated transplant program once the segment has been offered to candidates with a model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score of at least 33 and Status 1 candidates listed at liver transplant programs within 500 nautical miles (NM) of the donor hospital.

Under the proposed changes, the second segment of the liver would be offered to transplant programs within the same region as the donor hospital, rather than within 500 NM and with a MELD or PELD of at least 35 instead of at least 33. The resolution will also allow these changes to automatically revert to 500 NM and MELD or PELD of 33 upon implementation of the Acuity Circles policy.² The proposed changes would allow the units of distribution used in the variance to align with the units of distribution used in the allocation of deceased donor livers.

¹ OPTN Policy Notice, Split Liver Variance,

https://optn.transplant.hrsa.gov/media/3002/liver_policynotice_201906.pdf.

² OPTN Policy Notice, *Liver and Intestine Distribution Using Distance from Donor Hospital*, https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf.

Background

The Board approved a new closed variance for the allocation of the second segment of split livers at its June 10, 2019 meeting.³ The variance permits participating transplant programs to offer the second segment of the split liver to a candidate at the same transplant program or an affiliated transplant program once the segment has been offered to candidates listed at Status 1A or 1B or with a MELD or PELD of at least 33 at programs within 500 nautical miles (NM) of the donor hospital.

The original goal was to implement the variance on September 1, 2019. At that time, the Board expected the Acuity Circles policy, which uses NM as the unit of distribution for the allocation of deceased donor livers, to be in effect. However, the units of distribution for the allocation of deceased donor livers are still donation service area (DSA) and OPTN Region and the date when the units will be changed to NM distances is currently unknown. In order to implement the variance, the language for the variance must be updated so that the unit of distribution in the variance aligns with the unit of distribution for deceased donor livers.

When the variance was approved by the Board, the Board anticipated that the changes to the unit of distribution (approved as part of the Acuity Circles changes) might not be in place prior to the variance implementation date. Therefore, the Board directed the Executive Committee to ensure the language of the variance aligns with the units of distribution for deceased donor livers in place at the time of implementation and any time thereafter.⁴

So, on August 26, 2019, the Executive Committee amended the implementation date for the variance to tie it to the implementation date for Acuity Circles. This amendment allowed for time to either implement those changes or to circulate a change to the unit of distribution used in the variance to align in the meantime. The implementation date for the Acuity Circles policy is still uncertain, therefore the Liver Committee is pursuing a change to align the unit of distribution in the variance until such changes to the units of distribution are implemented.

Purpose

The variance, as approved, will allow participating transplant programs to use the second segment of a split liver for a candidate at the same transplant center or an affiliated transplant center after offering the segment to the candidates who would normally receive the first offers for that organ. This change will ensure that the group of candidates intended to be protected (those who would otherwise receive the offer) are protected.

In the planned distribution system, the candidates who would normally receive the offers earliest are those listed as Status 1A, 1B or with a MELD or PELD of 33 or higher within 500NM of the donor hospital.⁵ However, under the current distribution system, the candidates who would be in the earliest

³ OPTN Policy Notice, Split Liver Variance,

https://optn.transplant.hrsa.gov/media/3002/liver_policynotice_201906.pdf.

⁴ Transcript, *OPTN Board of Directors Meeting*, OPTN Open Session, June 10, 2019.

⁵ This is reflected in the first 14 classifications of the allocation table for non-DCD adult donors under 70 in the policy language for the approved changes to distribution that have not yet been implemented. OPTN Policy Notice, *Liver and Intestine Distribution Using Distance from Donor Hospital* at *Table 9-11: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old.*

sequences are those listed as Status 1A, 1B or with a MELD or PELD of 35 or higher within the region.⁶ Aligning the cutoff for who must receive offers before the remaining segment may be used at the same transplant program will ensure that the variance does not bypass the most urgent candidates who would otherwise receive offers of the remaining segment.

Overview of the Proposed Change

Under the proposed change, the second segment of livers split under this variance would be offered to candidates at transplant programs following the allocation sequences currently in effect. Therefore, the offers will be based on whether the candidates are listed within the same region as the donor hospital, rather than within 500 NM. The resolution will also allow the unit of distribution for the variance to automatically revert to 500 NM upon implementation of the Acuity Circles policy.

⁶ This is reflected in the first 14 classifications in the allocation table for adult donors. OPTN Policy *Table 9-11: Allocation of Livers from Deceased Donors at Least 18 Years Old.*

Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (example).

1 9.11.C Closed Variance for Any Segment Liver Transplantation

This is a closed variance. The OPTN Contractor maintains a list of participating transplant programs.
If a participating transplant program chooses to split an accepted liver, the program will decide which
segment of the liver to transplant into the intended recipient. The transplant program must notify the
host OPO of the remaining segment prior to transplanting the remaining segment. The OPO must then
offer the remaining segment to the following potential transplant recipients, using the same match run
used to allocate the liver:

Lower-ranked status 1A and 1B potential transplant recipients registered at any transplant hospital
 within 500 nautical miles of the donor hospital's the OPO's region

Lower-ranked potential transplant recipients with a MELD or PELD of 33 35 or higher that are
 registered at any transplant hospital within 500 nautical miles of the donor hospital the OPO's
 region

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15 If the remaining segment is not accepted for any of the potential transplant recipients in the bulleted

- 16 classifications listed above, the OPO must notify the participating transplant program that accepted the
- 17 liver. The participating transplant program may then transplant the remaining segment into a different,
- 18 medically suitable, candidate registered at the same transplant hospital or an affiliated transplant
- 19 program with an active pediatric liver component. If the first segment is accepted for a pediatric
- 20 potential transplant recipient, the participating transplant program may transplant the remaining
- 21 segment into a different, medically suitable, candidate at the same transplant hospital or an affiliated
- 22 transplant program. For purposes of this variance, participating transplant programs may only have one
- affiliated transplant program, and must identify the program they are affiliated with in their application
- 24 for the variance.
- 25

26 If the participating transplant program declines the remaining segment, the OPO may offer the

- 27 remaining segment to any lower ranked potential transplant recipients off the same match run used to
- 28 allocate the liver to the recipient of the first segment.
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These changes shall expire upon notice to members and implementation of the policy changes related to allocation that were approved by the OPTN Board of Directors on December 3, 2018 in the "Liver and Intestine Distribution Using Distance from Donor Hospital" proposal.

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