

Briefing to the OPTN Board of Directors on

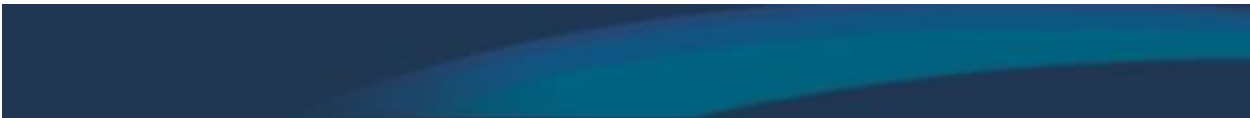
Aligning Units of Distribution in Closed Variance for Split Liver Transplantation

OPTN Liver and Intestinal Organ Transplantation Committee

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Aligning Units of Distribution in Closed Variance for Split Liver Transplantation

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| <i>Affected Policies:</i> | <i>9.11.C: Closed Variance for Any Segment Liver Transplantation</i> |
| <i>Sponsoring Committee:</i> | <i>Liver and Intestinal Organ Transplantation</i> |
| <i>Public Comment Period:</i> | <i>October 15, 2019 – November 14, 2019</i> |
| <i>Board of Director's Date:</i> | <i>December 3, 2019</i> |

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 will 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.

Purpose of Proposal

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 500 NM of the donor hospital.³ However, under the current distribution system, the candidates who would be in the earliest sequences are those listed as Status 1A, 1B or with a MELD or PELD of 35 or higher within the region.⁴ 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.

Background

The Board approved a new closed variance for the allocation of the second segment of split livers at its June 10, 2019 meeting.⁵ 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 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.⁶

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

³ 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*.

⁴ 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*.

⁵ OPTN Policy Notice, *Split Liver Variance*.

⁶ Transcript, *OPTN Board of Directors Meeting*, OPTN Open Session, June 10, 2019.

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.

Overview of Proposal

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 revert automatically to 500 NM upon implementation of the Acuity Circles policy.

Alignment with OPTN Strategic Plan

This proposal is aligned with the OPTN Strategic Plan goal of increasing the number of transplants because the variance is expected to increase the incentive to use a single liver to transplant two candidates.

Potential Fiscal Impact of Proposal

Members

This proposal does not alter the fiscal impact for members that was outlined in the original briefing paper for the split liver variance.⁷

OPTN

This proposal does not alter the fiscal impact for UNOS that was outlined in the original briefing paper for the split liver variance.⁸

Community Feedback

This proposal was supported during public comment. The American Society of Transplant Surgeons (ASTS), American Society for Transplantation (AST), American for Organ Procurement Organizations (AOPO), NATCO, and Society for Pediatric Liver Transplant (SPLiT) all supported the proposal. The Committee reviewed and discussed the results of public comment and concluded the public sentiment supports sending the proposal to the Board with no changes.

Implementation and Operational Considerations

OPTN actions

The UNOS Communications department will inform members of the proposed changes through targeted emails and notices.

⁷*Split Liver Variance*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2019, https://optn.transplant.hrsa.gov/media/2992/liver_boardreport_201906.pdf

⁸ *Id.*

Member actions

OPOs will need to familiarize their staff with the alternative allocation used in the variance and criteria for when it is used. Transplant hospitals participating in the variance will need to educate staff regarding when the variance may be used.⁹

Post-implementation Monitoring

Member compliance

The proposed language will not change the current routine monitoring of OPTN members. Any data submitted to the OPTN Contractor may be subject to review, and the OPTN Contractor will continue to review deceased donor match runs to ensure that allocation is carried out according to OPTN Policy. Members are required to provide documentation as requested.

Policy evaluation

This variance will be formally evaluated at approximately 1 year, 2 years, and 2 and a half years post-implementation.¹⁰

Conclusion

This proposal will amend the approved split liver variance to allow it to be implemented more expeditiously. With this change, the units of distribution used in the variance will align with the units of distribution used for deceased donor liver allocation. The second segment of livers split under this variance will 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 while the current liver allocation policy is in effect. This will allow the variance to begin operation without having to wait on implementation of the Acuity Circles policy.¹¹ These changes will automatically revert to 500 NM and MELD or PELD of 33 upon implementation of the Acuity Circles policy, so that alignment with units of distribution used in the allocation of deceased donor livers is maintained.¹²

⁹ For additional information on member actions, see OPTN Policy Notice, *Split Liver Variance*.

¹⁰ For additional information on evaluation of the variance, see OPTN Policy Notice, *Split Liver Variance*.

¹¹ OPTN Policy Notice, *Liver and Intestine Distribution Using Distance from Donor Hospital*.

¹² OPTN Policy Notice, *Liver and Intestine Distribution Using Distance from Donor Hospital*.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **9.11.C Closed Variance for Any Segment Liver Transplantation**

2 This is a closed variance. The OPTN Contractor maintains a list of participating transplant programs.

3
4 If a participating transplant program chooses to split an accepted liver, the program will decide which
5 segment of the liver to transplant into the intended recipient. The transplant program must notify the
6 host OPO of the remaining segment prior to transplanting the remaining segment. The OPO must then
7 offer the remaining segment to the following potential transplant recipients, using the same match run
8 used to allocate the liver:

- 9 ▪ Lower-ranked status 1A and 1B potential transplant recipients registered at any transplant hospital
10 within ~~500 nautical miles of the donor hospital's~~ the OPO's region
11 ▪ Lower-ranked potential transplant recipients with a MELD or PELD of ~~33~~ 35 or higher that are
12 registered at any transplant hospital within ~~500 nautical miles of the donor hospital~~ the OPO's
13 region

14
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
23 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.

29
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.

#

Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed “in accordance with §121.4”, which in turn incorporates the requirements in §121.8 that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.” This proposal meets the requirements of the Final Rule.

- **Shall be based on sound medical judgment:** The Committee proposed the variance based on sound medical judgment, including literature that supports potential positive outcomes from split liver transplantation (SLT) for more candidates than are currently transplanted as SLT.¹ Some of the challenges of SLT can be reduced when both segments are transplanted at the same program, or closely affiliated programs.² The variance will be used to test the theory that permitting more segments to remain at the same program will increase SLT, and the outcomes from the variance will be carefully considered to inform whether this approach should become policy for the nation.
- **Shall seek to achieve the best use of donated organs:** The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. The variance seeks to achieve the best use of donated organs by encouraging SLT, which will result in two transplants from one donated organ.
- **Shall be designed to avoid wasting organs:** Under the current policy, it is possible that partial livers are being used and the remaining segment is not being transplanted.³ This is viewed by the Committee as an example of organ wastage. The variance is designed to avoid wasting organs by encouraging the transplantation of both liver segments.
- **Shall be designed to avoid...futile transplants:** A futile transplant may occur if a recipient is transplanted with an organ that does not continue to function soon after transplantation. The variance does not incentivize futile transplants. Transplantation of both segments of a liver can result in successful post-transplant outcomes.⁴
- **Shall be designed to...promote patient access to transplantation:** The variance promotes liver candidate access to transplants by increasing the total overall number of livers available for transplant. Additionally, the variance is likely to result in better pediatric patient access to liver transplantation, because when a liver is split, at least one of the segments is typically used for a pediatric patient.⁵
- **Shall be designed to...promote the efficient management of organ placement:** A proposal that reduces logistical complications associated with procuring an organ and transporting it from the

¹ OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

² Wertheim, et al., “Major Challenges Limiting Liver Transplantation in the United States”.

³ OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

⁴ Hashimoto, et al., “Split Liver Transplantation in Adults”. V. Corno, et al. “Extended Right Split Liver Graft for Primary Transplantation in Children and Adults”. U. Maggi, et al., “Fifteen Years and 382 Extended Right Grafts from *in situ* Split Livers in a Multicenter Study: Are These Still Extended Criteria Liver Grafts?”

⁵ V. Corno, et al. “Extended Right Split Liver Graft for Primary Transplantation in Children and Adults”.

donor to the candidate promotes efficient management of organ placement. The variance promotes the efficient management of organ placement by reducing the transportation and coordination required in SLT cases by more specifically detailing when a transplant program can allocate the remaining segment to a candidate at the same transplant program or affiliated programs. Specifically, the proposed change to the variance promotes the efficient management of organ placement by ensuring that distribution within the variance is in line with the distribution system used for all deceased donor livers, and merely adapts that framework instead of creating a completely different approach just for the variance.

- Shall not be based on the candidate’s place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** A proposed variance may be based on a candidate’s residence or place of listing only to the extent required to achieve the considerations listed above. The variance considers geography with regard to the distribution of the remaining segment. The Committee proposed allocating the remaining segment to the most urgent candidates within 500 NM of the donor hospital before allocating directly to a candidate at the same program or affiliated program. This proposal seeks to alter the use of 500 NM so that the remaining segment is offered first to candidates within the same region as the donor hospital. For both 500 NM and region, the Committee decided to limit the allocation of the remaining segment to these proximate, urgent candidates in order to achieve the goals stated above, particularly making best use of donated organs, avoiding organ wastage, promoting access to transplantation, and efficient management of organ placement. The Committee determined that the liver is more likely to be split if the remaining segment will be transplanted by the transplant program that is performing the split⁶, therefore limiting the distance through which the remaining segment is offered is necessary to achieve the best use of donated organs as well as to avoid organ wastage. Likewise, as this would result in more SLTs, limiting the distance through which the remaining segment is offered will promote patient, particularly pediatric and small adult patient, access to transplantation.⁷ Finally, it would be inefficient to require the remaining segment to be offered according to the entire match run. It is difficult to find candidates to accept the remaining segment⁸, and requiring an exhaustion of the match run would likely result in more organ wastage, as a candidate would be less likely to be identified while the organ was still viable. The time required to do so, as well as the time required to transport the remaining segment from the donor to that candidate, would also likely result in more organ wastage, as there may be too much cold ischemic time on the organ at the point that it makes it to its final destination.⁹

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, Committee discussions did not demonstrate impacts on the following aspects of the Final Rule:

- Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
- Shall be reviewed periodically and revised as appropriate;

⁶ OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

⁷ V. Corno, et al. “Extended Right Split Liver Graft for Primary Transplantation in Children and Adults.”

⁸ Wertheim, et al., “Major Challenges Limiting Liver Transplantation in the United States.”

⁹ V. Corno, et al. “Extended Right Split Liver Graft for Primary Transplantation in Children and Adults.”

- Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.