

Notice of OPTN Policy Change

Review of Liver and Intestine Variances in OPTN Policy

Sponsoring Committee:	OPTN Liver and Intestinal Organ Transplantation Committee
Policies Affected:	<i>9.12.A: Open Variance for Segmental Liver Transplantation</i> <i>9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Liver</i> <i>9.12.C: Closed Variance for Any Segment Liver Transplantation</i> <i>9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico</i>
Public Comment:	August 3, 2022 - September 28, 2022
Executive Committee Approved:	October 26, 2022
Effective Date:	October 26, 2022

Purpose of Policy Change

There are four different variances, which test potential changes to OPTN policy on a smaller scale, related to the allocation of livers and intestines in OPTN policy. Two variances provide increased access to transplant for candidates registered in Hawaii (HI) and Puerto Rico (PR) due to their geographic isolation.^{1,2} The other two variances relate to the allocation of split liver segments, with the intent of increasing the number of split liver transplants.^{3,4} Prior to this policy change, each of these variances had a different expiration date. This policy change aligns the expiration dates of the four variances to expire upon implementation of continuous distribution of livers and intestines.

Alignment of the expiration dates allows for more consistent evaluation and administration and simplifies the OPTN Liver and Intestinal Organ Transplantation Committee's (the Committee) project portfolio as they focus on continuous distribution. The Committee will consider whether and how to incorporate the variances into continuous distribution.

Proposal History

This proposal extends and aligns the end dates for each of the four variances that currently exist in OPTN policy for the allocation of livers and intestines. The table below provides an overview of each of the variances:

¹ OPTN Policy: 9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers, as of June 2022

² OPTN Policy 9.12.A: Open Variance for Segmental Liver Transplantation, as of June 2022

³ OPTN Policy 9.12.C: Closed Variance for Any Segment Liver Transplantation, as of June 2022

⁴ OPTN Policy 9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico, as of June 2022

Table 1: Description of OPTN Policy 9.12 Variances

Variance	Description
<i>Policy 9.12.A: Open Variance for Segmental Liver Transplantation</i>	Allows transplant programs that transplant a right lobe or right tri-segment into an index candidate to transplant the left lobe or left lateral segment into another liver transplant candidate on the same match run at the same transplant program
<i>Policy 9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers</i>	Removes priority for O and B liver transplant candidates so that potential liver transplant recipients with any blood type within the same classifications for blood type O deceased donors in HI and PR
<i>Policy 9.12.C: Closed Variance for Any Segment Liver Transplantation</i>	Permits transplant programs in Region 8 to offer the second segment of a split liver for transplant into a liver transplant candidate at same transplant program after being offered to potential transplant recipients with a MELD or PELD 33+ and Status 1A or Status 1B within 500 NM of the donor hospital
<i>Policy 9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico</i>	Provides additional access to deceased donor livers for Status 1A or Status 1B or MELD or PELD 37+ liver transplant candidates in HI and PR due to geographic isolation

Summary of Changes

This change does not impact the substance of the variances themselves. The variances will continue to function as they have. The only change is related to the end dates of the variances, which are now extended and will expire upon implementation of continuous distribution of liver and intestines.

Implementation

Transplant programs already participating in the variances will continue to be required to submit data for the duration of the variances. Organ procurement organizations will need to be familiar with the variances and continue to work with transplant programs who are participating in the variances to allocate livers and intestines accordingly.

The OPTN will continue to work with members participating in the variances to ensure all required data is submitted and variances are monitored appropriately.

Affected Policy Language

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

The following variances are extended and will expire upon the implementation of continuous distribution of livers and intestines.

9.12 Variances

9.12.A Open Variance for Segmental Liver Transplantation

This variance only applies when a transplant program transplants a right lobe or right trisegment of the liver.

Under this variance, a transplant program may offer the remaining left lobe or left-lateral segment into a different, medically suitable, potential recipient registered at the same transplant hospital or an affiliated pediatric institution instead of offering the remaining segment to potential recipients at other transplant programs. The transplant program must determine potential recipient for the second segment by using the same match run used to allocate the right lobe or tri-segment. Additionally, the transplant program must document all refusals of potential transplant recipients that are prioritized ahead of the potential transplant recipient that received the second segment.

Each participating region or DSA must meet to review the results of the first ten segmental liver transplants performed as a result of this variance, and each ten thereafter. If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the variance exceeds three within any sequential twenty transplants, the variance at that transplant program will be put on hold until the transplant program can review results and surgical practices.

9.12.B Closed Variance for Allocation of Blood Type O Deceased Donor Livers

This is a closed variance that applies only to liver and liver-intestine organs allocated by the OPOs in Hawaii and Puerto Rico to potential transplant recipients registered at transplant programs in Hawaii and Puerto Rico, respectively due to geographic location. This variance supersedes the treatment of blood type O donors according to 9.8.C Allocation of Livers by Blood Type, and instead the OPO will allocate these blood type O organs to potential transplant recipients with any blood type within the same classification.

9.12.C Closed Variance for Any Segment Liver Transplantation

This is a closed variance. The OPTN 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
- Lower-ranked potential transplant recipients with a MELD or PELD of 33 or higher that are registered at any transplant hospital within 500 nautical miles of the donor hospital

If the remaining segment is not accepted for any of the potential transplant recipients in the bulleted classifications listed above, the OPO must notify the participating transplant program

that accepted the liver. The participating transplant program may then transplant the remaining segment into a different, medically suitable, candidate registered at the same transplant hospital or an affiliated transplant program with an active pediatric liver component. If the first segment is accepted for a pediatric potential transplant recipient, the participating transplant program may transplant the remaining segment into a different, medically suitable, candidate at the same transplant hospital or an affiliated 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 for the variance.

If the participating transplant program declines the remaining segment, the OPO may offer the remaining segment to any lower ranked potential transplant recipients off the same match run used to allocate the liver to the recipient of the first segment.

9.12.D Closed Variance for Liver Transplantation in Hawaii and Puerto Rico

This is a closed variance that applies only to liver and liver-intestine candidates registered at transplant programs in Hawaii or Puerto Rico, due to geographic location. This variance provides for additional classifications in the allocation sequences in Policies 9.8.E-9.8.J. The additional classifications apply to the following:

- Candidates registered at transplant programs in Hawaii when the transplant hospital is at or within 2,400 NM of the donor hospital.
- Candidates registered at transplant programs in Puerto Rico when the transplant hospital is at or within 1,100 NM of the donor hospital.

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