Notice of OPTN Policy Change

Aligning Units of Distribution in Closed Variance for Split Liver Transplantation

Sponsoring Committee: Policy Affected:

Public Comment: Board Approved: Effective Date: Liver and Intestinal Organ Transplantation 9.11.C Closed Variance for Any Segment Liver Transplantation October 15 - November 14, 2019 December 3, 2019 December 3, 2019

Purpose of Policy Change

This change aligns the units of distribution used in the Region Eight split liver variance with the units of distribution used in the allocation of deceased donor livers. With this change, the variance can be implemented immediately rather than waiting for the implementation of the Acuity Circles liver policy.

Proposal History

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 in OPTN Region 8 to offer the second segment of the split liver to a candidate at the same transplant program or an affiliated pediatric 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.

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. This proposal changes the units of distribution used in the closed split liver variance so that the units of distribution in the Board-approved variance align with the units of distribution for deceased donor livers.

This proposal to align the unit of distribution and permit implementation of the variance independently of implementation of Acuity Circles was circulated for public comment October 15, 2019 - November 14, 2019. It was approved by the Board on December 3, 2019.

¹ OPTN Policy Notice, Split Liver Variance,

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

Summary of Changes

This policy change requires the second segment of livers split by transplant programs participating in the Region Eight variance to 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 policy change 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 changes allow the units of distribution used in the variance to align with the units of distribution used in the allocation of deceased donor livers.

Implementation

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.

The OPTN will provide guidance regarding when the variance may be used. This variance will be formally evaluated approximately 1 year, 2 years, and 2.5 years post-implementation.

Affected Policy Language

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

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

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 program may transplant the remaining segment into a different, medically suitable, candidate at the same transplant program may transplant hospital or an affiliated transplant program. For purposes of this variance, participating transplant programs may only have one

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

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.

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.