

OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary November 19, 2019 Conference Call

James Trotter, MD, Chair James Pomposelli, MD, PhD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via teleconference on 11/19/2019 to discuss the following agenda items:

- 1. Region 8 Split Liver Variance
- 2. Revised Language: Clarification of Pre-Existing Liver Disease
- 3. Public Comment: Hawaii/Puerto Rico Variance
- 4. Public Comment: Enhancements to the National Liver Review Board (NLRB)

The following is a summary of the Committee's discussions.

1. Region 8 Split Liver Variance

The OPTN Board of Directors (BOD) approved a closed split liver variance at their meeting in June 2019. The variance that was approved utilized nautical miles (NM) as the units of distribution, which aligned with the units of distribution used in the Acuity Circles policy. Because it is unclear when the Acuity Circle policy will be implemented, the Committee sponsored a public comment proposal to align the units of distribution used in the variance with the units of distributions used in the allocation of deceased donor livers. The public comment period for the proposal closed on November 14 and the proposal is slated to be considered by the BOD during their meeting in December 2019.

Summary of discussion:

The Committee reviewed all public comments submitted for the proposal. They then reviewed the proposed policy language. The Chair clarified that the language would change back to using NM as the unit of distribution upon implementation of the Acuity Circles policy.

A formal vote was taken regarding: do you approve sending the proposal to align the units of distribution used in the closed split liver variance to the BOD?

Results were as follows: 13 (100%) Support, 0 (0%) Abstain, 0 (0%) Oppose

Next steps:

The BOD will consider the proposal during their meeting in December 2019.

2. Revised Language: Clarification of Pre-Existing Liver Disease

The Committee recently sponsored a public comment proposal to clarify the definition of pre-existing liver disease. During a previous meeting, Committee members suggested a few clarifying changes to the proposed language that went out for public comment.

Summary of discussion:

The Committee reviewed the updated language to ensure that it was as clear as possible.

A formal vote was taken regarding: do you approve sending the revised proposal to clarify the definition of pre-existing liver disease to the BOD for consideration?

Results were as follows: 14 (100%) Support; 0 (0%) Abstain, 0 (0%) Oppose

Next steps

The BOD will consider the proposal during their meeting in December 2019.

3. Public Comment: Hawaii/Puerto Rico Variance

Under the Acuity Circles policy, liver candidates listed in Puerto Rico and Hawaii will not receive any liver offers from outside of Puerto Rico and Hawaii, respectively, until they are offered nationally. For candidates in Hawaii and Puerto Rico who urgently need a transplant, there may not be a donor of compatible blood type within the time frame they need. The Hawaii-Puerto Rico Work Group has been discussing possible solutions for this situation.

Summary of discussion:

The Chair presented the recommended solution from the Hawaii-Puerto Rico Work Group to the Committee. The proposed solution was to include an additional unit of distribution of 2,400 NM between the transplant program and donor hospital for Status 1 and high model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) candidates in Hawaii and an additional unit of distribution of 1,100 NM between the donor and transplant hospital for Status 1 and high MELD or PELD candidates listed in Puerto Rico. This would involve uni-directional allocation of organs. Additionally, it was proposed as a variance.

The Committee reviewed data on the distances from donor hospitals to transplant hospitals for deceased donor liver transplants in Puerto Rico and Hawaii in the last seven years. The data showed that the majority of livers transplanted in Puerto Rico came from donor hospitals within 1,100 NM of the transplant program in Puerto Rico. The data also showed that the majority of livers transplants in Hawaii came from donor hospitals within 2,400 NM of the transplant program in Hawaii. The Committee reviewed maps showing which donor hospitals would be included in the proposed allocation sequences.

The Committee reviewed the proposed policy language. The Chair noted that the proposed allocation sequences would provide additional access to candidates listed as Status 1A/1B or with MELD/PELD of 37 or higher. The Chair also clarified that the variance would only apply if Acuity Circles is implemented. The Committee was informed that the proposed language would go out for special public comment so that it can be implemented expeditiously.

A formal vote was taken regarding: do you approve sending the proposed policy language for Hawaii and Puerto Rico out for special public comment?

Results were as follows: 14 (100%) Support; 0 (0%) Abstain, 0 (0%) Oppose

Next steps:

The proposal will be considered by the Policy Oversight Committee and the Executive Committee for a special public comment period.

4. Public Comment: Enhancements to the National Liver Review Board (NLRB)

The NLRB Subcommittee has discussed numerous ways to improve the NLRB since its implementation. The Committee reviewed the recommended enhancements during a previous meeting and is intending to sponsor a public comment proposal to get public input on the proposed changes to the NLRB.

Summary of discussion:

The NLRB Chair presented each of proposed improvements to the Committee for review.

When discussing the proposed change to the scope of NLRB review, a Committee member noted that it may be difficult to consider exceptions based on waitlist mortality because good data does not exist. The Committee member suggested adding language to the scope of review to allow reviewers to also consider waitlist dropout rates, instead of only waitlist mortality risk. The Committee agreed with adding this language to the scope of NLRB review.

The Committee had no additional comments on the proposed changes.

A formal vote was taken regarding: do you approve sending the NLRB policy, guidelines, and guidance changes out for public comment?

Results were as follows: 14 (100%) Support; 0 (0%) Abstain, 0 (0%) Oppose

Next steps:

The proposed changes will move forward for Policy Oversight Committee and Executive Committee approval for public comment.

Upcoming Meeting

- January 10, 2020
- February 7, 2020