

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
December 21, 2017
Conference Call

Julie Heimbach, MD, Chair
James Trotter, MD, Vice Chair

Introduction

The OPTN/UNOS Liver and Intestinal Organ Transplantation met via Citrix GoTo teleconference on 12/21/2017 to discuss the following agenda items:

1. Hepatocellular carcinoma (HCC) Policy
2. Review of Board of Directors Meeting and Follow-Up

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

1. HCC Policy

In June 2016, the Liver and Intestinal Organ Transplantation Committee agreed to policy language detailing extensions of HCC exceptions. *Policy 9.3.F.viii* includes the following: *In order for a candidate to maintain an approved exception, the transplant program must submit an updated MELD/PELD exception application every three months. The candidate will receive the additional priority until transplanted or is found unsuitable for transplantation based on the HCC progression.* As liver policy language was updated following the December 2017 Board of Directors meeting, changes to the extension policy for HCC were implemented. However, an oversight regarding the language on HCC extensions warrants re-examination and potentially amendment.

The current *Policy 9.3.F.viii* as of December 12, 2017 is as follows:

In order for a candidate to maintain an approved exception for HCC, the transplant program must submit an updated MELD/PELD exception application every three months. The candidate will receive the additional priority as long as they continue to meet initial eligibility requirements.

Committee members agreed that this policy language was meant to address candidates that progress outside of T2 criteria and would no longer qualify for automatic extensions. However, if candidates receive treatment (e.g., ablation therapy) and fall below T2 criteria, they should continue to receive automatic HCC extensions. The current policy language is similar to policy language that existed in the late 2000s in which many issues arose due to candidates seeking exceptions. If candidates do not meet eligibility requirements (i.e., the candidate was treated and their tumors no longer meet the criteria), they will no longer receive an exception and will need to go through regional review boards (RRB) for approval. This would, in essence, include a large number of patients at centers that follow a national trend of continuing treatment until there are no tumors. Committee leadership does not believe the intent of this policy change was meant to revert policy to language that caused difficulties in exception pathways for HCC patients. As such, the Liver and Intestinal Organ Transplantation Committee discussed what truly was intended from the most recent policy language changes to HCC exceptions.

Committee members voiced agreement that the current policy language and its subsequent implementation do not meet the Committee's intent. Committee members agreed that the intended effects of the policy were to apply to patients who progress beyond T2 criteria, therefore not qualifying for an automatic extension. Moreover, dropping below T2 criteria would

not result in the need for review if they initially were given the exception by meeting initial eligibility criteria. Committee members agreed that the policy language must be considerably more concise moving forward in order to correct this language.

Following this meeting, Committee leadership will reach out to Board leadership with regard to a quickened timeline, particularly as Committee members feel this change will negatively affect patient safety. This timeline will also include communications to centers and RRBs in order to make them aware of the situation and how the Committee is working to fix this known issue. Committee leadership will follow up with the Committee following discussions with Board leadership.

2. Review of Board of Directors Meeting and 2018 Follow-up

The Board of Directors (BOD) approved the *Redesigning Liver Distribution* proposal (35 yes, 3 no, and 1 abstention). There were no amendments to the proposal as a result of BOD discussion. The BOD supported the consensus built with the community and the Committee. Moreover, the BOD encouraged the Committee to continue discussing the role of geography in allocation moving forward. This charge was followed by the announcement of a newly formed Ad Hoc Geography Committee. This new committee will feature leadership from several committees as well as BOD members. The scope of the committee is being developed but, overall, the group will bring a recommendation to the BOD on the role of geography in organ allocation by the Summer 2018 BOD Meeting.

Moving into 2018, the Committee will be focused on a number of tasks. Most importantly, these tasks include the implementation of the National Liver Review Board (NLRB) and the changes to liver distribution. For the Liver Distribution Subcommittee, it is important to work on further revisions specifically for DSA/regions much higher than MMaT of 29. Overall, the Committee needs to discuss implementation decisions, review instructional and education efforts, and communicate the upcoming changes to your respective regions and institutions.

The Subcommittee Roster was shown during the meeting. This includes Committee member placement on the Liver Distribution Subcommittee and the Implementation Committee. If you have a strong preference for one subcommittee over another, please let Matthew Prentice know. Moreover, be on the lookout for emails seeking availability for upcoming meetings.

Upcoming Meetings

- TBD

Attendance

- **Committee Members**
 - Scott Biggins
 - Terry Box
 - Samantha DeLair
 - Michael Flood
 - Ryo Hirose
 - John Lake
 - Alyson Lewis
 - Willscott Naugler
 - Kevin O'Connor
 - Joseph Roth
 - Patricia Sheiner
 - Jennifer Watkins
 - William Chapman
 - Sue Dunn
 - John Goss
 - Julie Heimbach
- **HRSA Representatives**
 - Janet Kuramoto-Crawford
 - Marilyn Levi
 - Raelene Skerda
 - Robert Walsh
 - Monica Lin
- **SRTR Staff**
 - Alyssa Herreid
- **OPTN/UNOS Staff**
 - James Alcorn
 - Kimberly Combs
 - Ann Harper
 - Aaron McKoy
 - Elizabeth Miller
 - Joel Newman
 - Samantha Noreen
 - Liz Robbins Callahan
 - Melinda Woodbury