

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

June 4, 2021

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 Citrix GoToMeeting teleconference on 06/04/2021 to discuss the following agenda items:

1. Public Comment Proposal and Vote

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

1. Public Comment Proposal and Vote:

The Committee reviewed items slated for public comment in August 2021, including:

- Updates to National Liver Review Board (NLRB) Guidance
- Updates to Hepatocellular carcinoma (HCC) Policy
- Alcohol-associated Diagnoses

Summary of discussion:

The Committee discussed the proposed changes to NLRB policy and guidance.

1. Included in the upcoming proposal

HCC Guidance: Immunotherapy- A member commented that when data emerges immunotherapy should be reviewed again. The Committee agreed with the NLRB Subcommittee's (the Subcommittee) proposed language to add to HCC guidance: "Evidence for the use of immunotherapy as a down- staging or bridging therapy is preliminary. However, based on the published the data in transplant and non-transplant setting, the use of immunotherapy does not preclude consideration for an HCC exception."

HCC Guidance: Candidates Resected more than Two Years Ago- A member explained that current guidance is unclear if candidates resected more than two years ago need to wait six months to receive MMaT-3. A committee member suggested that sections 1 and 5 should be adjacent to one another. Members agreed that it should be clarified that section 1 is referring to patients not treated with resection, while section 5 refers to those treated with resection. A member asked if a patient who was ablated, but recurred after 2 years would lose their exception. Another member suggested that this should be addressed as part of the Subcommittee's future work.

The Committee agreed with the Subcommittee's recommendation to clarify guidance so that candidates resected more than two years ago do not need to wait 6 months to receive MMaT-3. The following language will be added to section 5: "This includes candidates who initially presented with T2 resectable HCC and who underwent complete resection more than 2 years ago." Additionally, these numbered sections will be changed to bullet points in the policy language.

HCC Policy: Clarify Chest Computed Tomography (CT) Requirement- The Committee agreed with the Subcommittee's recommendation to add language to make it clear that a chest CT is only required prior to an initial exception request.

Encephalopathy Guidance- The Committee agreed with the following updated language: "Hepatic encephalopathy (HE) is a complication of chronic liver disease with an associated mortality independent of Model for End- Stage Liver Disease (MELD) scoring. Presently no additional MELD priority for HE is recommended in the absence of a widely available, reliable, objective assessment of severity." References were also updated.

The Committee agreed with the Subcommittee's recommendation of no changes to the guidance for ascites, gastrointestinal (GI) bleeding, and hepatic hydrothorax.

2. Discussed but not included in the proposal

Candidates listed at multiple programs- Currently, candidates listed at multiple programs can be approved for a non- standard exception at one program but not approved at another. The Subcommittee discussed methods for addressing the situation, but it was determined that due to existing barriers, any resolution would require additional time and discussion. One member noted that one program can request an exception for a candidate, but a second program may not do the same based on their own clinical opinion. Therefore, approved exceptions should not follow candidates to subsequent programs. Another member responded that an approved exception at one program should trigger exception approval at the second program and agreed with the 6-month time period. The Committee may consider this issue at a future date.

Candidates beyond downstaging- The Subcommittee determined there was insignificant evidence to make a recommendation for a revision to guidance for candidates beyond downstaging and will review explant pathology data when it becomes available. The Committee agreed with this recommendation.

3. Future work identified

Align with LI-RADS Classifications- The Subcommittee will discuss potential future changes to align OPTN HCC classifications with current LI-RADS classifications.

Guidance for Diffuse Ischemic Cholangiopathy (IC)- The Subcommittee will discuss recommendations for a higher score to encourage the use of DCD donors and consider moving IC from guidance to policy to allow for automatic exceptions. The Subcommittee submitted a data request to inform future decisions and will review this as part of the next round of diagnoses. A member noted that the data request was made to determine if these candidates have a higher rate of waitlist mortality.

Alcohol- associated Diagnoses- This project aims to update liver diagnoses on the Transplant Candidate Registration (TCR)/ Transplant Recipient Registration (TRR) to allow for more complete and accurate data collection on transplant candidates/recipients with alcohol- associated liver disease. In prior discussions, the proposed diagnoses were 1) alcohol- associated cirrhosis and 2) alcohol-associated cirrhosis or hepatitis with less than 6 months of abstinence. A member noted that updating the response options to these new options will encourage those entering diagnosis data to make a more accurate selection. Another member suggested that instead of indicating if a candidate has over or under 6 months of abstinence, the specific duration of abstinence should be collected. UNOS staff reminded the Committee that such a field would be considered new data collection that could be addressed in future work, but would not fit into this project's public comment timeline. At the conclusion of their discussion, the Committee agreed upon "alcohol associated cirrhosis without acute alcohol associated hepatitis" and "acute alcohol-associated hepatitis with or without cirrhosis" as the proposed new diagnoses.

The Committee voted on the changes included in the upcoming proposal.

Vote: 17- Support, 0- Abstain, 0-Oppose

Next steps:

- The proposal will be sent to public comment in August 2021.

Upcoming Meetings

- July 2, 2021

Attendance

- **Committee Members**
 - Peter Abt
 - Diane Alonso
 - Sumeet Asrani
 - Kimberly Brown
 - James Eason
 - Alan Gunderson
 - Julie Heimbach
 - Bailey Heiting
 - James Markmann
 - Greg McKenna
 - Shekhar Kubal
 - Ray Lynch
 - Peter Matthews
 - Mark Orloff
 - James Pomposelli
 - Jorge Reyes
 - James Trotter
- **HRSA Representatives**
 - Raelene Skerda
- **SRTR Staff**
 - Michael Conboy
 - John Lake
- **UNOS Staff**
 - Nicole Benjamin
 - Roger Brown
 - Matt Cafarella
 - Julia Foutz
 - Betsy Gans
 - Chelsea Haynes
 - Savannah Holmes
 - Joel Newman
 - Samantha Noreen
 - Kelley Poff
 - Matt Prentice
 - Niyati Upadhyay
- **Other Attendees**
 - Scott Biggins (Incoming Vice Chair, July 2021)
 - Samantha Taylor
 - James Sharrock