

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
Meeting Summary
September 9, 2021
Conference Call**

James Trotter, MD, NLRB Chair

Introduction

The National Liver Review Board Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on 09/09/2021 to discuss the following agenda items:

1. Updated Project Scope
2. Review Ischemic Cholangiopathy Guidance
3. HCC Candidates Treated and Recur
4. LI-RADS

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

1. Updated Project Scope

The Subcommittee discussed the current project's scope.

Summary of discussion:

UNOS staff explained that due to the number of items slated for OPTN January 2022 public comment and limited IT resources, the Subcommittee should shift their project scope to focus on high impact, low effort diagnoses. The Subcommittee will review diagnoses in NLRB guidance, as they do not involve any implementation or programming by IT.

Next steps:

The Subcommittee will focus their efforts on Ischemic Cholangiopathy (IC), Polycystic Liver disease (PLD), post-transplant complications, and Hepatocellular Carcinoma (HCC) guidance and Liver Imaging Reporting and Data Systems (LI-RADS) for the upcoming January 2022 public comment period.

2. Review Ischemic Cholangiopathy Guidance

The Subcommittee discussed updates to IC guidance.

Summary of discussion:

The Subcommittee reviewed the IC data presented during the last meeting. They observed that from 2015 to 2020, the number of candidates ever requesting an exception for IC was 62. A member commented that this number may decrease if new graft survival metrics are implemented because programs may be more reluctant to accept marginal grafts. A member commented that regional differences and previous denials may influence if a program decides to request an exception for IC. A member noted that the data showed DCD recipients had a high mortality rate, but this mortality is dominated by candidates who are Status 1A. This member continued that overall, there is little difference in waiting list mortality outside of Status 1A. The Subcommittee aims to encourage the use of DCD donors and provide a safety net, as data shows that the risk involved with using these types of

donors is higher. The Subcommittee came to a consensus that when a candidate meets the criteria in guidance for IC, the candidate should be given some form of priority.

Next steps:

The Subcommittee will continue this conversation at a future meeting.

3. HCC Candidates Treated and Recur

The Subcommittee discussed updates to guidance for HCC candidates who are treated and recur.

Summary of discussion:

The Subcommittee reviewed draft language regarding exceptions for HCC candidates. The Subcommittee discussed the addition of language that would allow candidates with stage T2 HCC who are treated, but recur to be exempt from the six month waiting period, so long as they have documentation (biopsy or LI-RADS 5) confirming their prior diagnosis. A member commented that the purpose of the six month waiting period is to examine the biology of the tumor. They added that the tumor biology might not be the same as the candidate's prior HCC diagnosis, especially if the recurrence takes place a few years after treatment. The Subcommittee agreed they would need to establish a timeframe and suggested three years, but determined they would need more evidence to make this recommendation.

Next steps:

The Subcommittee will continue this conversation at a future meeting.

4. LI-RADS

The Subcommittee discussed aligning LI-RADS and OPTN HCC classifications.

Summary of discussion:

A member asked about the next steps in this process. UNOS staff explained that the alignment with LI-RADS involves the OPTN changing some of its data labels on initial and extension exception forms. They continued that this could impact the scope of the project depending upon if the new language will simply replace the old response options or if the new language would involve new data collection. The Subcommittee expressed their opinion that the new fields will simply replace the old response options and does not entail any new data collection.

Next steps:

The Subcommittee will continue this conversation at a future meeting.

Upcoming Meeting

- October 14, 2021

Attendance

- **Subcommittee Members**
 - Sophoclis Alexopoulos
 - Scott Biggins
 - Kimberly Brown
 - Alan Gunderson
 - Allison Kwong
 - Greg McKenna
 - Jim Trotter
 - Kym Watt
- **HRSA Representatives**
 - Katie Audette
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Andrew Wey
- **UNOS Staff**
 - Nicole Benjamin
 - Matt Cafarella
 - Julia Foutz
 - Jennifer Musick
 - Megan Oley
 - Kelley Poff
 - Niyati Upadhyay
 - Leah Slife