

**OPTN Liver and Intestinal Transplantation Committee
OPTN National Liver Review Board (NLRB) Subcommittee
Meeting Summary
March 11, 2021
Conference Call**

**Julie Heimbach, MD, Subcommittee Chair
James Trotter, MD, Committee Chair
James Pomposelli, MD, PhD, Committee Vice Chair**

Introduction

The OPTN National Liver Review Board (NLRB) Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference 03/11/2021 to discuss the following agenda items:

1. Review Hepatocellular Carcinoma (HCC) Guidance
2. Primary/Secondary Sclerosing Cholangitis (PSC/SSC)
3. Ongoing Review of NLRB Diagnoses- Next Steps

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

1. Review HCC Guidance

The Subcommittee discussed current HCC guidance and potential changes.

Summary of discussion:

A Subcommittee member announced that the Policy Oversight Committee (POC) approved the Liver Committee's project to continue to review NLRB diagnoses in policy and guidance. The project will seek Executive Committee approval in April.

A member solicited feedback from the Subcommittee on the following possible HCC guidance and policy changes:

- Guidance: Longer waiting periods for candidates beyond downstaging criteria
- Guidance: Statement on patients treated with immunotherapy and successfully downstaged
- Policy: Clarify requirement for chest Computed Tomography (CT)

A member asked if there was a way to investigate what percentage of Liver Imaging Reporting and Data System (LI- RAD) 4 lesions were confirmed as HCC. A member responded that this type of data has not been analyzed since 2013 and is due for review.

A member suggested that there should be a pathway to transplant for candidates with large tumors outside of UCSF, but that the required waiting period should be consistent with tumors of comparable risk such as a branch chain, portal vein, and ruptured HCC. The Subcommittee discussed the challenges of writing guidance that would account for tumors just outside of UCSF and those much farther outside UCSF. A member shared that two years ago their program expanded to T3 without downstaging. A member commented that a modification such as this would fall under the umbrella of a policy change, not guidance. A member reported that the 6 month waiting period felt appropriate. A member asked if there was any data to support a longer observation period. The Subcommittee agreed that they should look further into the literature before determining if any changes should be made to guidance.

The Subcommittee discussed adding a statement on downstaging with immunotherapy to guidance. A member commented that they were unsure the Subcommittee could give accurate guidance, as there is not much published research on the topic. The Subcommittee will search for literature on this topic and discuss during their next meeting.

A member commented that the requirement for chest CT has caused some confusion at his program. Subcommittee members agreed that the CT policy should not be changed, but should be clarified.

Next steps:

The Subcommittee will look into literature pertaining to downstaging criteria and immunotherapy.

2. Primary/Secondary Sclerosing Cholangitis Data Request

UNOS staff presented the results of the OPTN Liver and Intestinal Organ Transplantation Committee's data request for candidates with PSC and SSC.

Summary of discussion:

The Subcommittee reviewed the waiting list drop out rates for adult, liver – alone waiting list registrations overall and broken out by Model for End-stage Liver Disease (MELD) score groups. A member asked how the overall graph shows Alcoholic Hepatitis (AH) as the diagnosis with the highest dropout rate when this is not reflected in any breakout graph other than MELD less than 15. Research staff explained that the number of patients with AH in the data set is much lower than other diagnoses. When combined with the other diagnoses AH does have the highest drop out rate, but this result is due to sample size. Members noted that Nonalcoholic Fatty Liver Disease (NAFLD) have a higher drop out rate while PSC patients have a lower rate when compared to the other diagnoses.

Next steps:

Research staff will finish presenting this data at an upcoming Subcommittee meeting.

3. Ongoing Review of NLRB Diagnoses- Next Steps

The NLRB Chair will provide next steps in the process for reviewing NLRB diagnoses in policy and guidance.

Next steps:

The Subcommittee will review this agenda item during an upcoming meeting.

Upcoming Meeting

- April 8, 2021

Attendance

- **Subcommittee Members**
 - Kimberly Brown
 - Alan Gunderson
 - Julie Heimbach
 - James Markmann
 - Greg McKenna
 - James Pomposelli
 - Jorge Reyes
 - James Trotter
- **HRSA Representatives**
 - Marilyn Levi
 - Adriana Martinez
- **SRTR Staff**
 - John Lake
 - Ryo Hirose
- **UNOS Staff**
 - Nicole Benjamin
 - Matt Cafarella
 - Betsy Gans
 - Jennifer Musick
 - Samantha Noreen
 - Kelley Poff
 - Liz Robbins
 - Leah Slife
 - Karen Williams