

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
December 12, 2023
Conference Call**

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 12/12/2023 to discuss the following agenda items:

1. National Liver Review Board (NLRB) Project Prioritization

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

1. National Liver Review Board (NLRB) Project Prioritization

The Subcommittee discussed and prioritized potential project ideas.

Summary of discussion:

Contrast-enhanced Ultrasound (CEUS)/LI-RADS Updates

This project idea was brought forward through a collaboration with the American College of Radiology. This project idea had previously been incorporated into a prior project, *NLRB Updates Related to Transplant Oncology*, however was put on hold in order to devote resources to modify the Adult HCC Review Board to become an Adult Transplant Oncology Review Board.

This project would propose to add contrast-enhance ultrasound as an acceptable adjunct diagnostic tool into hepatocellular carcinoma (HCC) policy. Additionally, the project could review the potential to modify HCC policy for imaging criteria to align with LIRADS imaging terminology.

Members did not add input on this project idea.

Standard Criteria for HCC Exceptions

This project idea aims to review the current standard criteria in Policy 9.5.1: *Requirements for HCC MELD or PELD Score Exception* to determine whether there are areas for improvement that would allow for more automatic approvals for HCC standard exceptions.

Members did not add input on this project idea.

Update Non-Alcoholic Steatohepatitis (NASH)/Non-Alcoholic Fatty Liver Disease (NAFLD) Nomenclature

This project would update the system in order to align with current terminology related to metabolic dysfunction-associated steatotic liver disease (MASLD) nomenclature.

A member emphasized that it would be important to add metabolic and alcohol related/associate liver disease (MetALD) as it is a distinct diagnosis. The member explained that adding this to the diagnosis codes would aid in analyzing outcomes separately from MASLD in the future. Another member estimated that this may impact at most 10% of liver candidates. A member disagreed, citing that it may

be more since these candidates are currently grouped in with alcohol-related liver diseases rather than NASH, due to clinical cutoffs.

Another member agreed that this is an important topic to address. A member added that MASLD is considered one of the biggest indications for liver transplantation, emphasizing the need for this project to be prioritized.

Review NLRB Guidance

The Vice Chair suggested that the Subcommittee could develop score recommendations for non-standard exceptions for each diagnosis in the NLRB guidance documents. The Vice Chair noted this project may be important to reduce variance of assigned scores for non-standard exceptions.

A member voiced their preference for this project because they serve on the NLRB and feel that determining score recommendations for some diagnoses is difficult and standard guidance would be helpful. Another member agreed, noting that from an equity perspective, it is necessary, and they believe that a candidate's score should not be dependent on how good of a non-standard exception narrative is written.

The Vice Chair suggested parsing out the project so that Subcommittee members can focus on the area or diagnoses that interest them.

Address Impact of Terlipressin on Model for End-Stage Liver Disease (MELD) Scores/Modify Lab Update Schedule

This project would explore the potential to mitigate the effect of Terlipressin on MELD scores. A member commented that they do not have any further input than they previously provided during the OPTN Liver & Intestinal Organ Transplantation Committee's preliminary discussion on this topic at the October 16th Committee meeting. Another member stated that it would be worthwhile to review the lab update schedule in Policy 9.2: *Status and Laboratory Values Update Schedule*. A member voiced support for reevaluating the MELD score update schedule.

Updating Status 1A Pre-existing Liver Disease Definition

The project idea would address whether candidates with pre-existing liver diseases without evidence of cirrhosis are eligible for Status 1A.

Members did not add input on this project idea.

Auto-approve Non-standard Exception Extensions

This project idea would seek to develop an automatic approval system for non-standard exception extensions in order to lessen the manual review of the NLRB.

Members did not add input on this project idea.

Alcohol-Associated Hepatitis

This project would explore the topic of alcohol-associated hepatitis and whether there is an action for the OPTN Liver & Intestinal Organ Transplantation Committee to take. A member indicated that professional societies are addressing this issue, and they feel that professional societies should continue to be the entities to issue guidance. They continued, noting that mandating an addiction specialist to be part of transplant teams is overbearing and may create more disparities since not all transplant programs will have access to alcohol addiction specialists. Another member voiced their agreement, noting that the Subcommittee should not be dictating clinical care and that all transplant programs do not have the same resources.

A member agreed, adding that the equity piece is important. The member explained that it is more difficult to transplant a candidate with exception for a cancer diagnosis than it is to transplant a candidate with alcohol-associated hepatitis because of the lack of criteria. Another member replied that the reason there are more criteria for cancer-related diagnoses are due to differences in post-transplant outcomes and organ utility considerations.

A member commented that there is not enough information regarding standard of care or best practices, so therefore enacting a mandate would be difficult. The member suggested that perhaps the Subcommittee consider what data is necessary to determine the problem and solution. Another member voiced their beliefs that post-transplant testing might be appropriate to understand outcomes if this were a project the Subcommittee were to take on.

A member commented that this topic is important. The member stated that they conduct their research on this topic but recognize that there is not enough evidence to develop a mandate. The Vice Chair noted that the Subcommittee could create guidance. A member commented that that information varies depending on who is asked and there is not a consensus on what is acceptable. A member chimed in, adding that this is a complex topic, and this project may be better to approach in the future once more information and evidence is published related to this topic.

Another member suggested that Subcommittee members could request feedback from their local hepatologists to gather input on how to address this topic as a potential project. A member commented that if different people are asked, there will be varying opinions, as this becomes more of a values judgement. They suggested that the Subcommittee could try to address variability among transplant program practices. Another member agreed with previous sentiments, citing that regardless of the pathologic diagnosis, the concern is transplanting candidates with alcohol-related liver disease when there is limited sobriety. They said they envision this project to be more of a guidance document that emphasizes best practices rather than a policy mandate.

A HRSA representative voiced their surprise upon learning that some liver transplant programs do not have access to addiction management and treatment programs. They suggested collecting data from liver transplant programs that do have alcohol addiction specialists.

A member asked what is the Subcommittee trying to accomplish regarding the topic of alcohol-associated hepatitis. The Vice Chair responded that there is a lot of variability in transplant program practices and suggested that the OPTN's role may be to determine how organs should be allocated. A member responded that the allocation system should be based on medical acuity and waitlist mortality, and if post-transplant outcomes are acceptable then organs are being allocated appropriately. The member noted their uncertainty about how to determine regulations for alcohol-associated hepatitis. They noted that they believe that it becomes a question of equivalency since alcohol is pervasive in our society and it is not illegal, therefore they are having a difficult time determining what the Subcommittee would accomplish with this project. The Vice Chair commented that this is something the Subcommittee should continue to discuss as data and evidence evolves.

A member stated that the number of alcohol-associated hepatitis cases has increased significantly in the past couple of years and advised that the Subcommittee review the outcomes of this population. Another member agreed that looking at the data would help aid their decision to take on this project. A member indicated that the outcomes for their recipients are excellent, as they are young and otherwise healthy, therefore the data may inaccurately reflect their severity of illness since they have strong outcomes. A member noted that the Subcommittee must be prepared to respond to the community concerning this issue. Another member stated that there is not sufficient evidence and suggested that

the NLRB could propose data collection regarding the dates or the length of sobriety and isolate and analyze the outcomes from the population that partake in early sobriety.

The Vice Chair indicated their desire for a data registry since a lot of data is transplant program-specific and other transplant programs cannot see how everyone else is doing.

Next Steps:

The Subcommittee will continue to prioritize and refine project ideas.

Upcoming Meetings

- January 9, 2024, at 2 pm ET (teleconference)

Attendance

- **Subcommittee Members**
 - Allison Kwong
 - Chris Sonnenday
 - Joseph DiNorcia
 - Kym Watt
 - Neil Shah
 - Shimul Shah
 - Sophoclis Alexopoulos
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jack Lake
 - Katie Audette
 - Simon Horslen
- **UNOS Staff**
 - Cole Fox
 - Erin Schnellinger
 - Katrina Gauntt
 - Kayla Balfour
 - Megan Oley
 - Meghan McDermott
 - Niyati Upadhyay