

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee**

June 11, 2024

Conference Call

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 06/11/2024 to discuss the following agenda items:

1. Update on New Project: Update NLRB Guidance + Further Alignment with Liver Imaging Reporting and Data System (LI-RADS)
2. Member Recognition

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

1. Update on New Project: Update NLRB Guidance + Further Alignment with Liver Imaging Reporting and Data System (LI-RADS)

The Subcommittee received an update and the next steps on their new project focused on updating the Adult Model for End-Stage Liver Disease (MELD) Exception Review guidance document and updating hepatocellular carcinoma (HCC) policy and guidance to align with LI-RADS 5 terminology as well as the addition of contrast-enhanced ultrasound. The Subcommittee submitted a data request and began developing requirements related to contrast-enhanced ultrasound and LI-RADS alignment.

Summary of discussion:

Updating NLRB Guidance

The Subcommittee requested the following metrics to help inform their decisions regarding developing score recommendations for each diagnosis in NLRB guidance.

- Number and proportion of registrations who apply for at least one non-standard exception by exception diagnosis
- Number and proportion of registrations who apply for at least one non-standard exception by case outcome (approved, withdrawn, denied, etc.). For registrations who submitted multiple non-standard forms, the outcome of their most recent form will be used.
 - Among these registrations, the distribution of score adjustment requested
- Number and proportion of registrations with approved non-standard exceptions removed from the OPTN waiting list by removal reason and exception diagnosis
- Number and proportion of registrations transplanted with approved non-standard exceptions
 - If transplanted with an approved non-standard exception, the distribution of exception points relative to MMaT (and allocation MELD at transplant, if available)
 - If transplanted with an approved non-standard exception, time-to-transplant (in days)

One member commented that they are interested in reviewing the results of the data request. The member added that this data will help accurately inform score recommendations. The Subcommittee

began signing up in small groups (1-2 members per diagnosis) and will research their designated diagnoses.

Contrast-Enhanced Ultrasound (CEUS) & LI-RADS Alignment

The Subcommittee began discussing requirements for adding CEUS as an acceptable adjunct diagnostic tool for HCC.

The Subcommittee reviewed Policy 9.5.I.i: *Initial Assessment and Requirements for HCC Exception Requests*.

One member commented that they felt that it makes sense to put a time component in the policy language, as tumors may grow. The member added that the time component is also important to reassess because then it may indicate that the candidate now falls within the downstaging criteria. The member suggested three-months as the timeframe. Another member agreed that three months is reasonable and added that computed tomography (CT) scans are also performed every three months, so it would make sense to have these testing modalities performed in the same cadence.

Members agreed that CEUS should only be used for evaluation of lesions and not for determining metastatic disease, extrahepatic spread, or macrovascular involvement.

The Subcommittee reviewed Policy 9.5.I.iii: *Lesions Eligible for Downstaging Protocols* and discussed whether any additional considerations are necessary for utilizing CEUS in the context of downstaging.

A member asked whether it is validated to use CEUS in the context of treated lesions. Another member stated that the American College of Radiology helped develop these recommendations. A member replied that the American College of Radiology released guidelines for using CEUS on treated lesions this year.

A member asked whether a transplant program determines which imaging modality results they wish to use. The member explained that there may be situations where the CEUS results are within Milan criteria while the CT results may be just outside of the criteria. Another member replied that as it is currently recommended that would be feasible, but the Subcommittee could further discuss whether this situation should be allowable.

A member noted it would be important to have the same three-month time period for downstaging protocols for consistency.

The Subcommittee reviewed Policy 9.5.I.vii: *Extensions of HCC Exceptions* and discussed whether any additional considerations are necessary for utilizing CEUS in the context of extending extensions.

A member stated that there are no specific considerations for the use of CEUS to consider when extending an HCC exception.

One member indicated that their transplant program is currently using CEUS, mostly for diagnostic dilemmas. They felt that they had avoided performing a couple of biopsies, thanks to CEUS.

The Subcommittee reviewed Policy 9.5.I.vi: *Imaging Requirements for Class 5 Lesions* and discussed aligning imaging classification criteria with LI-RADS.

A member said the current criteria may be complicated for transplant program staff filling out the HCC exception forms. Another member responded that when the reports do not have the granular criteria listed, the staff will often reach out to the hepatologists or surgeons which can be cumbersome. A member stated that most reports utilize LI-RADS terminology and will state "LI-RADS 5" if it meets the imaging criteria for LI-RADS 5.

When the Subcommittee was asked where the LI-RADS 5 criteria should be referenced, a member replied that they felt that having it in guidance makes more sense as compared to policy, since it would be a long process to change, even if it is a minor edit. Another member agreed.

Next steps:

Updating NLRB Guidance

The small groups will report during the upcoming Subcommittee meetings.

CEUS & LI-RADS Alignment

The Subcommittee will continue to refine the policy language modifications to align with the intent of adding CEUS and LI-RADS 5. They will then review the final language and system requirements prior to Committee review and vote.

2. Member Recognition

The Subcommittee recognized outgoing members and thanked them for their service on the NLRB.

Summary of discussion:

There was no discussion regarding this agenda item.

Upcoming Meetings

- TBD

Attendance

- **Subcommittee Members**
 - Aaron Ahearn
 - Allison Kwong
 - Joseph DiNorcia
 - Neil Shah
 - Shimul Shah
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Ben Schumacher
 - Cole Fox
 - Erin Schnellinger
 - Meghan McDermott
 - Niyati Upadhyay