

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

**April 9, 2024  
Conference Call**

**James Pomposelli, MD, PhD, Chair**

## **Introduction**

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 4/9/2024 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. Update on Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) Terminology
3. NLRB Monitoring Report
4. NLRB Transplant Oncology Public Comment Language Review

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.

#### Summary of discussion:

There were no decisions regarding this item.

A member suggested making the diagnosis scores Median Model for End-Stage Liver Disease (MELD) at Transplant (MMaT) -3, or at least making that the default score. The Chair voiced their concern that doing that may negatively impact hepatocellular carcinoma (HCC) patients and that some of these diagnoses may be more urgent than a score of MMaT-3 will reflect. A member agreed, recommending that the scores have a recommendation per group, rather than having one score for each. The member clarified that the score of MMaT-3 would be a base score, with the ability to be adjusted as necessary for each diagnosis and patient. A member agreed that MMaT-3 would be a good base score, adding that there will likely be little data on most of these diagnoses. The Subcommittee was reminded that this information can be decided after the OPTN Policy Oversight Committee reviews and approves this project, as they do not need to know the score recommendations, rather they need to know the size of the project.

#### Next steps:

This project will go to the OPTN Policy Oversight and Executive Committees for consideration in May. If approved, the Subcommittee will submit a data request to help inform score recommendations, review

the literature to update language and content, and develop policy language and review system requirements to incorporate LI-RADS-related updates.

## 2. Update on Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) Terminology

The Subcommittee received an update regarding the MASLD terminology change which includes the following:

- Update diagnosis codes on the Transplant (TCR) and the Transplant (TRR) to align with current MASLD terminology.
  - Deactivate: *Cirrhosis: Fatty liver (NASH)*
  - Add: *Cirrhosis: Metabolic Steatohepatitis (MASH)*
  - Add: *Cirrhosis: Metabolic and alcohol-related/associated liver disease (MetALD)*
- Update HCC exception forms to allow for automatic approval of candidates utilizing new HCC treatments that otherwise meet standard criteria.
  - Add *Histotripsy*
  - Add *Other*
- OPTN Executive Committee approved these changes on March 19

### Summary of discussion:

The Subcommittee requested monitoring reports at 6 months and 1-year post-implementation.

When asked about monitoring recommendations for changes at 6 months and 1-year post-implementation, one member commented that they did not think much would come out of it and that is likely low stakes, and other members agreed. The Chair agreed to submit a request for monitoring, however, they noted that not a lot of data or information may come from it.

### Next steps:

Education will be developed and communicated with the community upon implementation. The Subcommittee will receive monitoring reports when ready.

## 3. NLRB Monitoring Report

The Subcommittee reviewed the NLRB monitoring report including modifications to guidance as well as new additions.

### Data summary:

The report monitors the impact of seven policy, guideline, or guidance changes for the National Liver Review Board (NLRB). The seven changes occurred across two public comment NLRB enhancement proposals and are listed below:

- Policy Language: Standard Criteria for Portopulmonary Hypertension Exceptions - Implemented October 7, 2021
  - The number of initial and extension forms submitted for portopulmonary hypertension exception cases decreased in the post-policy era.
  - The proportion of portopulmonary hypertension exception cases that were automatically approved increased for both initial and extension cases.
- Operational Guidelines: Pediatric Appeals Review Team (ART) - Implemented October 7, 2021
  - There were 17 pediatric ART cases in the post-guideline implementation era: 13 were approved or withdrawn prior to decision and 4 were denied.

There were no events in the pre-guideline implementation era as the committee was formed upon the implementation date.

- Guidance: Polycystic Liver Disease - Implemented February 9, 2021
  - Overall, the proportion of liver alone transplant recipients with an exception for polycystic liver disease decreased and the proportion of simultaneous liver kidney (SLK) transplants with a polycystic liver and kidney disease exception increased in the post-guidance era.
- Policy Language: Hilar Cholangiocarcinoma (CCA) Standardized Exception Criteria - Implemented October 7, 2021
  - Exception cases evaluated below include all exception forms under CCA diagnosis.
  - The number of exception forms for CCA decreased in the post-policy era.
  - The proportion of exception cases that were NLRB reviewed also decreased.
- Guidance: Pediatric Updates - Implemented July 15, 2021
  - The number of pediatric exception cases and the proportion of pediatric cases approved remained consistent across eras.
- Guidance: Neuroendocrine Tumors (NET) - Implemented July 15, 2021
  - The number of exception cases for candidates with neuroendocrine tumors decreased in the post-guidance era and the proportion of those approved also decreased.
  - Guidance: Primary Sclerosing Cholangitis and Secondary Sclerosing Cholangitis - Implemented July 15, 2021SummaryThe number of cases regarding primary sclerosing cholangitis or secondary sclerosing cholangitis increased in the post-guidance era.
  - The proportion of cases accepted increased.

Summary of discussion:

No decisions were made regarding this agenda item.

A member pointed out that they felt the changes reflected in primary and secondary sclerosing cholangitis were interesting. A member suggested using National Language Processing to analyze the narratives provided, as well as the responses provided from reviewers in future reports. They added that the reason for the decreased volume of cases being submitted could be due to the adjustment from the regional system.

Next steps:

The Subcommittee will continue to review monitoring reports as they become available.

**4. NLRB Transplant Oncology Public Comment Language Review**

The Subcommittee discussed public comment received on the *NLRB Updates Related to Transplant Oncology* proposal that was out for public comment in Winter 2024.

Summary of discussion:

The Subcommittee agreed to incorporate changes into the NLRB Transplant Oncology language: “6 months from diagnosis or last treatment of tumor stability meaning less than or equal to 3 cm, no new lesions, or extrahepatic disease before applying for exception”.

The Subcommittee discussed public comment feedback regarding the drafted guidance for intrahepatic cholangiocarcinoma.

A member asked whether the exceptions for intrahepatic cholangiocarcinoma could have a six-month wait similar to hepatocellular carcinoma (HCC) exceptions. Another member responded that a six-month wait cannot be enforced for intrahepatic cholangiocarcinoma as it is a non-standard exception requiring NLRB review. The Chair stated that the language should clearly note that the candidate should demonstrate six-month stability to ensure good biology.

One member pointed out that during public comment, some feedback reflected confusion. A member suggested defining stability, meaning “tumors within less than or equal to three centimeters and no new lesions”. The Chair recommended clarifying that there should be no extrahepatic disease when applying for the initial exception.

A member mentioned that available data is related to treating the lesions locoregionally and then transplanting them six months later, but agreed with the previous member’s verbiage if any edits are to be made. The member noted that the point is that the intrahepatic cholangiocarcinoma should be treated prior to applying for an exception. Another member indicated that they are comfortable with the proposed modification for defining stability.

A member suggested modifying the criteria to become two distinct criteria; one criterion to address therapy and another criterion to address tumor stability.

A member voiced their concerns that they do not want to become too prescriptive with language and terminology. One member reminded the Committee that this is from public comment and that these comments were representative of a small portion of all comments received. Several members agreed on modifying the language to have a separate criterion state “6 months from time of diagnosis or from last treatment of tumor stability, meaning less than or equal to three centimeters, no new lesions, or extrahepatic disease before applying for an exception.”

#### Next steps:

The Subcommittee will present the proposed post-public comment modifications to the OPTN Liver & Intestinal Organ Transplantation Committee.

#### **Upcoming Meetings**

- May 14, 2024 @ 2 pm ET (teleconference)

## Attendance

- **Subcommittee Members**
  - Jim Pomposelli
  - Allison Kwong
  - Joseph DiNorcia
  - Kym Watt
  - Scott Biggins
  - Shimul Shah
  - Sophoclis Alexopoulos
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Simon Horslen
- **UNOS Staff**
  - Cole Fox
  - Erin Schnellinger
  - Katrina Gauntt
  - Kayla Balfour
  - Meghan McDermott