OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
Meeting Summary
September 26, 2024
Conference Call

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board (the Subcommittee) met via WebEx teleconference on 09/26/2024 to discuss the following agenda items:

1. Non-Standard Exception Data Report
2. Project Development: Update NLRB Guidance + Further Alignment with Liver Imaging Reporting and Data System (LI-RADS)

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

1. Non-Standard Exception Data Report

A brief overview of Non-Standard Exception Data was presented using the following.

- 13 Non-Standard exception diagnosis with forms submitted between July 1, 2022, and December 31, 2023
- Used the most recent form for each person's unique diagnosis
- Analyses are based on OPTN data as of September 13, 2024, and are subject to change based on future data submission or correction

Summary of discussion:

No decisions were made regarding this agenda item.

There was surprise and confusion over the number of approved exceptions for Hepatic Encephalopathy as Hepatic Encephalopathy should not award exceptions according to guidance. One member suggested that Hepatic Encephalopathy be coded into the system to automatically not approve an exception for this condition.

The Subcommittee wished to discuss this more when there was more time. They decided to introduce this data report to the Liver and Intestinal Organ.

Next steps:

The Subcommittee will provide a full update to the Liver and Intestinal Organ Transplantation Committee and review the standard exception data report on October 9th.
The Subcommittee will talk about why Hepatic Encephalopathy is getting Non-Standard exceptions Transplantation Committee at the in-person meeting on October 9th and talk about why Hepatic Encephalopathy was getting Non-Standard exceptions.

2. Project Development: Update NLRB Guidance + Further Alignment with Liver Imagining Reporting and Data System (LI-RADS)

The Chair gave an overview of the work being done in matching LI-RADS language and imaging classification criteria. The Subcommittee reviewed NLRB Guidance for Hepatic Hydrothorax, Small for Size Syndrome, Neuroendocrine Tumor, and Hemorrhagic Telangiectasia.

Summary of discussion:

Include any decision points for the specified agenda item.
Decision #1: Accepting proposed changes to the guidelines for Hepatic Hydrothorax
Decision #2: Accepting proposed changes to the guidelines for Small for Size Syndrome
Decision #3: Renaming Small for Size Syndrome Guidance
Decision #4: Accepting proposed changes to the guidelines on Neuroendocrine Tumor
Decision #5: Accepting proposed changes to the guidelines Hemorrhagic Telangiectasia

Decision #1 – Accepting the proposed changes to guidelines for Hepatic Hydrothorax

The Subcommittee decided to modify Hepatic Hydrothorax guidelines to only require one culture, or one cell count and to specify an overall volume over a period of time. They also changed the language of the guidelines concerning transjugular intrahepatic portosystemic shunts (TIPS). The Subcommittee endorsed these changes and needs to decide priority point values later once data for this non-standard exception is available. The proposed changes to language and requirement are as follows.

“Per AASLD guidelines, TIPS placement in patients with MELD scores as low as 18 in some studies and more clearly with MELD scores >21 incurs higher mortality risk, and the beneficial outcome in hydrothorax highly relates to liver function and age.”

“At least 1 L of pleural fluid removed four separate times in last 4-6 weeks; report date and volume of each pleural fluid removal. If drainage catheter in place, documentation must be performed/witnessed by a provider or RN.”

The Subcommittee decided that TIPS is not a requirement but rather should be under background information because it may be that TIPS can’t always be done. The change in the requirement for pleural fluid is due to challenges coordinators faced under previous requirements.

No alternative changes were considered at this time.

Decision #2 – Accepting proposed changes to the guidelines for Small for Size Syndrome

The Subcommittee looked at a proposal to include risk factors for Small for Size Syndrome (SFSS) and adopt a score-based grade of SFSS in guidance for non-standard exceptions. The Subcommittee decided to include risk factors of SFSS but not make them requirements to get exception points. They also decided to utilize the proposed score-based grade for SFSS and use Grade C at post operation day seven and day fourteen test results for Bilirubin and International Normalized Ratio (INR) as the requirement for priority points. The subcommittee decided to mockup these new changes and review this guidance again later.

The Subcommittee decided to list risk factors for SFSS in the guidance, such as ascites, cholestasis, and worsening renal failure, but not to include them in the requirements for exception as they felt the Bilirubin and INR results would be sufficient to justify the degree of sickness and warrant additional

priority for the patient. The subcommittee decided to use the definition of Grade C as the requirement for granting additional priority points under this non-standard exception. They felt that these scores indicated the patient was sick enough to warrant additional priority points at Median Meld at Transplant (MMaT) as these patients are even sicker than some HCC patients. The definition of Grade C SFSS is as follows.

Grade C = T.Bill > 10mg/dl and INR > 1.6 at day seven and T.Bil > 20mg/dL at day fourteen

The Subcommittee considered including Grade B SFSS with certain conditions as qualifying for the exception as well. They determined that any patient with Grade B SFSS would likely have renal dysfunction and low albumin and that these patients would have a high enough Model for End-Stage Liver Disease (MELD) score to get transplant without warranting additional priority. As a result, they did not include Grade B SFSS as qualifying for additional priority.

Decision #3 – Renaming Small for Size Syndrome Guidance

During the discussion on Small for Size Syndrome guidance the Chair felt that Small for Size Syndrome was a misnomer and that Small for Size was not a clear term. The Subcommittee decided to rename this guidance Early Allograft Dysfunction (EAD) in Reduced Size Livers (Small for Size Syndrome).

The Subcommittee felt it was possible to have the same conditions of Small for Size Syndrome in larger grafts. They felt Small for Size Syndrome was old nomenclature and by changing the title and keeping Small for Size Syndrome in parentheses they could clear up confusion and shift to the more accurate term Early Allograft Dysfunction.

The Subcommittee considered renaming this guidance Early Allograft Dysfunction in split livers but felt that reduced size livers was a more widely encompassing term.

Decision #4: Accepting proposed changes to the guidelines on Neuroendocrine Tumor

The Subcommittee considered cleaning up the guidelines for neuroendocrine tumors. They decided to remove bi-lobar as benefiting from MELD exception points and remove content about MRI or CT scan criteria. They decided the guidance instead should be based on Positron Emission Tomography (PET) scan with dotatate or liver biopsy if the PET scan is unclear. The Subcommittee also decided to change Mitotic KI67 rate to less than twenty percent and to take out the requirement that tumor metastatic replacement should not exceed fifty percent of the total liver volume.

The Subcommittee agreed this section just needed to be cleaned up. They felt MRI's and CT scans were no longer necessary to be included in this guidance because PET scans with dotatate are used instead. They felt current available data supported changing the Mitotic KI67 rate to less than twenty percent. Finally, there was some discussion on if the requirement that tumor metastic replacement should not exceed fifty percent of the total liver volume should be cut. According to one member the most current data suggested that it should be a requirement. The Subcommittee felt however that fifty percent was not measurable and somewhat arbitrary. They decided to remove that requirement.

No other options were considered at this time.

Decision #5: Accepting proposed changes to the guidelines Hemorrhagic Telangiectasia

The Subcommittee decided to add a condition that right heart catheterization and symptoms of heart failure could be used for case documentation. They also decided to use a tiered approach so that those with Class C or Class D heart failure may warrant MMaT while those with Class A or Class B heart failure

warrant MMaT -3 priority. The Subcommittee also chose to drop portal hypertension from requirements.

The Subcommittee decided that using the current classification of heart failure would provide greater detail and more stringent guidelines and that a two-tier system for heart failure would help determine appropriate priority for patients. They decided to drop portal hypertension to avoid conflating two different conditions. One member pointed out that there is a possibility under the heart failure classification system that in practice most patients will end up getting MMaT priority. The Subcommittee decided to go ahead with the tiered approach and monitor the results in the future to see if that possibility manifests.

The Subcommittee decided against including recurrent hospitalization as criteria so as not to incentivize patients to be hospitalized multiple times in circumstances where they don't need to be in the hospital. They also decided to use the current classification system of heart failure rather than just reoccurring heart failure as criteria to provide further clarity.

Next steps:

The Subcommittee will decide priority points for Hepatic Hydrothorax once they review the data on non-standard exceptions.

The Subcommittee will look at the cleaned-up version of the revised guidelines on Neuroendocrine Tumors.

The Subcommittee will look at a revised mockup of Small for Size Syndrome guidelines, now to be Early Allograft Dysfunction in Reduced Size Livers (Small for Size Syndrome).

The Subcommittee will look at Late Vascular Complications and Diffuse Ischemic Cholangiopathy and make decisions on how to combine those two sets of guidelines.

Upcoming Meeting

- October 24, 2024 @ 3PM ET (teleconference)

Attendance

- **Subcommittee Members**
  - James Pomposelli
  - Scott Biggins
  - Allison Kwong
  - Neil Shah
  - Aaron Ahearn
  - Michael Kriss
- **UNOS Staff**
  - Emily Ward
  - Jesse Howell
  - Benjamin Schumacher
  - Betsy Gans
  - Joel Newman
  - Niyati Upadhyay