OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
August 22, 2024
Conference Call

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 08/22/2024 to discuss the following agenda items:

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

The Subcommittee discussed their new project and focused on potential modifications to the Adult Model for End-Stage Liver Disease (MELD) Exception Review guidance document. Members presented preliminary reviews of specific guidance sections and reported out recommendations on potential modifications.

Summary of discussion:

Hepatic Hydrothorax

A member suggested condensing the opening section as it currently provides information on how to diagnosis hepatic hydrothorax which is not relevant to the criteria suggested for accessing a MELD exception. The member stated that adding updated survival data could help inform the justification narratives and review. The member also suggested adding updated literature references in this section.

The member spoke with transplant coordinators to receive additional feedback as they were aware the current guidance for hepatic hydrothorax was very cumbersome for transplant coordinators who are submitting the justification narratives. The member stated that transplant coordinators often have to spend a lot of time tracking down information for the criteria because some of it has occurred prior to referral. The member suggested that if a candidate has ascites, then it is usually clear that they have hepatic hydrothorax candidates so there should be the ability to document that and have it included in the criteria. The member added that if a candidate does not have ascites, then perhaps the criteria related to albumin gradient is necessary in order to assure that it is transitive fluid.

The member suggested that guidance suggesting two cultures to rule out infection may be too much and suggested modifying it to one culture or negative cell count to rule out infected fluid, but the member pointed out that this still may not be a way to identify parapneumonic fluid. The member stated that a criterion for a CT or MRI may be useful in determining if there is no infection and no cancer. A member agreed that performing one culture or cell count should be sufficient. The Chair

stated that if the cell count is high, the transplant program should have to prove that it is not from the lung or plera meaning that imaging would be helpful in those situations.

The member also suggested updating the guidance related to thoracocentesis as it is currently too rigid. The member suggested that having guidance on pleral fluid removal as opposed to thorocentsis may provide more flexibility as well as having guidance about the volume removed over time. A member agreed and stated that the criterion should ensure that it is recurrent. The Chair agreed that having the criteria provide guidance on an overall volume over a set period of time makes more sense.

The member affirmed that the other criteria in guidance for hepatic hydrothorax remain relevant.

A member asked for a suggested score recommendation. Another member responded that it would likely be hard to justify anything higher than MMaT minus three. The Subcommittee will use the upcoming data report to help inform a final score recommendation.

Another member asked whether guidance should specify that transplant programs should document that this is an ongoing problem to retain the exception. A member agreed suggested three-months would be consistent with other exception extensions.

Primary Sclerosing Cholangitis and Secondary Sclerosing Cholangitis

A member noted that the guidance is clear and concise as it had recently been updated in 2021. The member noted that there is not a score recommendation and that one should be added. The member suggested that MMaT minus three may be appropriate and in some cases MMaT might even be warranted.

Another member noted that the criterion related to bacterial growth may be too restrictive. The member stated that it is sometimes difficult to fit two bacteremias in the timeframe. A member asked whether they are advocating to modify it to one. The member responded that they were not but were acknowledging some outlier situations.

Another member stated that individuals diagnosed with a highly-resistant infectious organism might require a higher score recommendation. A member agreed and stated this population is dichotomous. Another member asked whether the guidance should be modified to be more stringent and provide a higher score recommendation or if the guidance should remain relatively the same and have a lower score recommendation. Another member stated that the guidance could be separated and offer two different score recommendations with associated criteria. Other members agree that candidates with multi-drug resistant and multiple hospitalizations should receive a higher score recommendation. A member asked whether there is data to support this stratification. The member advocated for having the guidance become more stringent for a higher score recommendation rather than distinguishing two separate populations. The Chair agreed and suggested it could be a combination of criteria to be met instead of all criteria.

Another member noted that this exception is not as utilized as it was intended to be and stated they would not want to make the criteria more stringent.

A member asked why there was a criterion related to cirrhosis. The member noted that not all Primary Sclerosing Cholangitis candidates have cirrhosis.

Members agreed that if a candidate has a highly-resistant infectious organism that the transplant programs should not have to continue to confirm this for the extensions.

A member stated that if a candidate has two hospitalizations and one documentation of sepsis or bacteremia then that is adequate. The Chair stated that unintended consequences should be considered based on the dichotomous nature of this population.

Late Vascular Complications

A member asked whether severe graft dysfunction should be defined.

Another member noted that the criteria in this section related to ischemic cholangiopathy is different than the NLRB guidance section for ischemic cholangiopathy.

A member asked whether this section could be removed. The member explained that candidates with late complications are biliary which means they would fall into one of the other exception pathways. Another member responded that a sentence could be added to the ischemic cholangiopathy section that states that a cause of ischemic cholangiopathy could be a late vascular complication and those candidates could apply for an exception.

A member stated that the complication is the problem, not the reason for having the complication. The member explained that if a candidate meets the criteria, then they should receive the exception, regardless of the type of complication. The member stated these candidates likely have similar waitlist mortalities and warrant similar exception scores.

Another member suggested that this could be added to the *Primary Sclerosing Cholangitis and Secondary Sclerosing Cholangitis se*ction. A member disagreed stating that there are situations where a candidate is diagnosed with hepatic artery thrombosis (HAT) at 21 days and it should not be necessary to wait for them to develop cholangitis. Another member stated that the Committee previously discussed updating the policy criteria for HAT standard exceptions to extend the timeframe. The member stated the Committee remains interested in making this modification.

A member suggested creating a post-transplant cholangiopathy section to encompass all the various clinical situations.

Another member stated that the specifying DCD should be removed as the same type of cholangiopathy can develop with a DBD transplant.

A member suggested that anatomic criteria should be added to this section as well because some candidates may not meet the infectious criteria but would meet anatomic criteria and should be receiving an exception. Another member stated that some of those candidates improve over time and may not need additional access to transplant. A member stated the criteria could specify that it is a type of refractory longitudinal problem related to their vasculature.

Members agreed this section should be combined with the guidance section for ischemic cholangiopathy.

Next steps:

The Subcommittee will continue to develop the project.

Upcoming Meetings

- September 26, 2024 (teleconference)

Attendance

- **Subcommittee Members**
  - Aaron Ahearn
  - Allison Kwong
  - Chris Sonnenday
  - Jim Pomposelli
  - Neil Shah
  - Scott Biggins
  - Shimul Shah
- **UNOS Staff**
  - Ben Schumacher
  - Cole Fox
  - Jesse Howell
  - Joel Newman
  - Meghan McDermott
  - Niyati Upadhyay
- **Other Attendees**
  - Kym Watt
  - Lloyd Brown