

OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary October 20, 2021 Conference Call

James Pomposelli, MD, PhD, Chair Scott Biggins, MD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/20/2021 to discuss the following agenda items:

- 1. Review of National Liver Review Board (NLRB) Diagnoses and Update to Alcohol-Associated Diagnoses
- 2. Project Portfolio Review
- 3. Ongoing Review of NLRB Diagnoses
- 4. Update on PELD/Status 1B Project
- 5. Improving the MELD Score LSAM Results
- 6. Hawaii and Puerto Rico Blood Type Variances
- 1. Review of National Liver Review Board (NLRB) Diagnoses and Update to Alcohol-Associated Diagnoses

The Committee reviewed public comment feedback and voted to send the proposal to the OPTN Board of Directors (BOD) for consideration.

Summary of discussion:

The Committee was asked if there were any comments or questions on the guidance and policy language as presented. There were no comments.

The Committee was asked if anyone was opposed to sending this proposal forward to the BOD for consideration. None were opposed.

Vote: 20- Support, 0- Abstain, 0- Oppose

Next steps:

Review of NLRB Diagnoses and Update to Alcohol-Associated Diagnoses will go to the OPTN BOD for consideration in December 2021.

2. Project Portfolio Review

The Committee reviewed their current and future project portfolio.

Summary of discussion:

A member asked for clarification on the implementation date of the Median Model for End-Stage Liver Disease (MELD) at Transplant (MMaT) around the Donor Hospital and Sorting policy. UNOS staff informed the Committee that the anticipated implementation timeframe is mid- 2022.

Next steps:

The Committee will continue to prepare the projects slated for the January 2022 public comment period.

3. Ongoing Review of NLRB Diagnoses

The Committee discussed the next round of NLRB updates slated for public comment in January 2022.

Summary of discussion:

The Committee gave feedback on proposed language for the next round of NLRB diagnoses.

Hepatocellular carcinoma (HCC):

A member asked for clarification on HCC language pertaining to patients who have been resected and recur within 24 months. The Committee felt 24 months was not the appropriate timeframe and recommended that "More than 6 months, but less than 60 months" would be more appropriate for these patients. The Committee recommended other minor changes to HCC language.

Ischemic Cholangiopathy (IC):

The Committee agreed with the NLRB subcommittee's recommendation that qualifying prior DCD recipients should be eligible for a MELD exception equivalent to MMaT.

Polycystic Liver Disease (PLD):

The Committee recommended that an objective measure should be developed to define "moderate to severe protein calorie malnutrition". They suggested the language should be inclusive with multiple measures for identifying malnutrition. These measures could include sarcopenia, grip strength, upper arm circumference, etc.

Liver Imaging Reporting and Data System (LI-RADS):

The Committee had no changes to the proposed language.

Next steps:

First, the NLRB subcommittee will finalize proposed changes. Then in November the Committee will vote to send the proposed changes out for public comment in January 2022.

4. Update on PELD/Status 1B Project

The Committee received an update on the Pediatric End-Stage Liver Disease (PELD)/Status 1B project.

Summary of discussion:

Model for End-Stage Liver Disease (MELD)/PELD Threshold:

A member asked if there was a PELD score used to determine waitlist mortality vs. operative mortality. The presenter responded that it is difficult to determine this because usually liver disease is the main driver of pediatric candidate mortality and that these recipients have a high post-operative survival. A couple of members voiced support for the removal of the MELD/PELD threshold.

Sorting within Status 1B:

A member asked for clarification of the 1B sorting points system. The presenter explained that the purpose of assigning 15 points to candidates with chronic liver disease is to ensure these candidates will be sorted ahead of tumor candidates in most circumstances. They added that a tumor candidate might be sorted ahead of a chronic liver disease candidate if this tumor candidate has significantly more

waiting time and/or is blood type compatible. A member clarified that the point system for blood type and waiting time already exists within 1B sorting and the PELD/Status 1B work group is suggesting the addition of a diagnosis sorting category.

Updating the PELD score: PELD- Creatinine (Cr)

The PELD Cr score includes 2.82 additional points to account for age-adjusted mortality. The presenter explained that the PELD/Status 1B work group supports adding points on top of the age-adjusted mortality points to the PELD Cr score with the goal of reducing pediatric waitlist mortality, but did not reach a clear consensus on how many points should be added. A member asked about the basis for adding these points. The presenter responded that as the number of points added to pediatric patients' PELD score increases, the pediatric waitlist mortality decreases. Members commented that adding more points to the PELD Cr score could improve pediatric access to transplant but this could be incorporated into continuous distribution or accomplished by encouraging the splitting of livers. The Committee felt that simply adding more points onto PELD Cr may contribute to inaccuracies in the prediction of mortality.

Updating priority rankling for adolescent candidates: Meld -> PELD:

A member noted that adolescents have been doing well using MELD scores and asked if this switch to PELD Cr is necessary given these results. The Committee compared the potential costs and benefits of switching adolescents from MELD to PELD Cr. The PELD/1B work group plans to request a resource estimate and discuss further.

Next steps:

The PELD/1B work group will review all Committee recommendations and discuss further at a later date.

5. Improving the MELD Score LSAM Results

The Committee reviewed the results of the liver simulated allocation model (LSAM) request and discussed options for improving the MELD score.

Summary of discussion:

A member voiced support for the addition of albumin to the MELD 3.0 model. They explained that while the potential for manipulation of albumin exists, the risk is relatively low. This member continued that without the inclusion of albumin, there is potential for MELD inflation. The Committee agreed that albumin should be included in the MELD 3.0 model. In November, the Committee will finalize and vote on which MELD 3.0 model to put out for public comment.

A member explained the recommendation for adding a field to the candidate demographic information form asking if the candidate's current sex is the same as his or her birth sex. This will allow the physician and candidate to be able to accurately document the candidate's current sex. The Committee agreed with this direction and noted the importance of developing guidance surrounding the issue in the future. A member suggested that the new field should not be required as it will pertain to so few candidates.

Next steps:

The Committee will move this project forward to January 2022 public comment.

6. Hawaii and Puerto Rico Blood Type Variances

The Committee discussed the Hawaii/Puerto Rico ABO blood type variance.

Summary of discussion:

This variance is set to expire in February 2022. The Committee reviewed data from the first 18 months of the variance and determined that additional data is needed to make a more informed policy recommendation.

The Committee voted to extend the Hawaii and Puerto Rico Blood Type Variance for two additional years.

Vote: 20- Support, 0- Abstain, 0- Oppose

Next steps:

The Committee will recommend that the BOD extend this variance for another two years.

Upcoming Meeting

• November 5, 2021

Attendance

• Committee Members

- o Alan Gunderson
- o Allison Kwong
- o Sumeet Asrani
- Derek DuBay
- o Diane Alonso
- o Greg McKenna
- o James Eason
- o James Markmann
- o James Trotter
- o James Pomposelli
- o Jennifer Kerney
- Jorge Reves
- o Kym Watt
- o Marl Orloff
- o Pete Abt
- o Peter Matthews
- o Raymond Lynch
- o Scott Biggins
- o Sophoclis Alexopoulos
- o Kimberly Brown

• HRSA Representatives

- o Jim Bowman
- o Raelene Skerda
- SRTR Staff
 - o Davis Schladt
 - o John Lake
 - o Katie Audette
 - o Tim Weaver
 - o Ryutaro Hirose
- UNOS Staff
 - o Matt Cafarella
 - o Kelley Poff
 - o Amber Wilk
 - o Chelsea Haynes
 - o Darren Stewart
 - o Joel Newman
 - o Julia Foutz
 - o Lean Slife
 - o Liz Robbins
 - o Matt Prentice
 - o Niyati Upadhyay
- Other Attendees
 - o Emily Perito
 - o Juan Del Rio Martin
 - o Nicolas Wood