

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

November 15, 2024

Conference Call

Scott Biggins, MD, Chair

Shimul Shah, MD, MHCM, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via WebEx teleconference on 11/15/2024 to discuss the following agenda items:

1. Review and Vote: Update NLRB Guidance + Further Alignment with Liver Imaging Reporting and Data System (LI-RADS)
2. Discussion and Review: Single Organ Acceptance Policy Memo
3. Continuous Distribution: Determine Research Questions for Modeling – Medical Urgency

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

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

Presentation Summary

The Committee reviewed a summary of changes to several documents before voting on sending these proposed changes to the Policy Oversight Committee. The summary is as follows:

Adult Meld Exceptions for Transplant Oncology

- Add table for LI-RADS 5 criteria, add CEUS criteria table, update tables for computed tomography (CT) scan and magnetic resonance imaging (MRI) criteria
- Add score recommendations and/or changes to Neuroendocrine Tumors, Hepatic Epithelioid Hemangioendothelioma, Hepatic Adenomas
- Reorder intro/table of contents

Adult MELD Exception Review

- Add score recommendations and/or changes to Budd Chiari, Hepatic Hydrothorax, Hereditary Hemorrhagic Telangiectasia, Polycystic Liver Disease, Primary Sclerosing Cholangitis or Secondary Sclerosing Cholangitis, Metabolic Disease, Early Allograft Dysfunction (EAD) in Reduced Size Livers (Small for Size Syndrome), Diffuse Ischemic Cholangiopathy
- Remove: Portopulmonary Hypertension, Late Vascular Complications

Policy 9.5.A: Requirements for cholangiocarcinoma (CCA) Model for End-Stage Liver Disease (MELD) or Pediatric Model for End-Stage Liver Disease (PELD) Score Exceptions clarifications

- Adds contrast-enhanced ultrasound as an acceptable adjunct diagnostic tool for LI-RADS 5, in addition to CT or MRI

- Additional changes to require multiphase vs dynamic (current policy) imaging

National Liver Review Board (NLRB) Operational Guidelines

- Non substantial updates to align to June 2024 approved, not yet implemented guidance
- Clarifies adult requests are not reviewed by Pediatric Review Board

Summary of Discussion:

Decision #1: The Committee unanimously voted yes in support of sending the proposed changes to NLRB guidance and Policy 9.5.A to the Policy Oversight Committee.

Number of Votes Yes: 15

Number of Votes No: 0

Number of Votes Abstaining: 0

There was no discussion of this agenda item.

Next steps:

- OPTN Executive Committee will review and vote on public comment slate
- Winter 2025 public comment: January 21st – March 19th

2. Discussion and Review: Single Organ Acceptance Policy Memo

Presentation Summary

The Committee previously discussed a problem with transplant centers seeing highly sick liver transplant patients die before transplant under the single organ acceptance policy. A recap of the issue and potential solutions are as follows:

Problem

- Concern over loss of Status 1A/High MELD patients under the new Single Organ Acceptance policy
- Lack of time for second offer
- Small portion of population results in lack of data (monitoring report will be released end of November 2024)

Solution/Action Item

- Send memo of concern to Executive Board and Organ Procurement Organization Committee (OPO) to request that the policy be modified to allow for two acceptances for candidates with a MELD/PELD score above 37 or who are Status 1, as these are the most urgent candidates

Summary of Discussion:

Decision #1: The Committee decided to add an additional alternative solution to their memo.

The Vice Chair pointed out that the proposed solution in the memo is a compromise to the single acceptance organ policy as the only patients that transplant centers could hold two organs for would be very ill, likely hospitalized, and few in numbers.

One Member mentioned that there was an inflection point in survival rates for patients with MELD of 35 and suggested the cut off MELD number for holding two organs should be 35 rather than 37. The Vice Chair responded that the top tier of patients is MELD 37 and that including anything below that may be asking for too much.

Two Members mentioned that during the previous meeting when this topic was brought up that the Committee had discussed imposing a time window on how long two organs could be held for a single patient based on operating room (OR) times. The Committee discussed not limiting themselves by this time window because liver transplant surgeons often do not know if an organ will work until they see it in the OR. Others on the Committee felt that imposing the time window would help alleviate OPO concerns and that not to include it would be a failure to address late turn downs which was part of what led to the Single Organ Acceptance policy in the first place. One member proposed the Committee needed to add to the memo that the OR time for each organ needs to be set and within eight hours of each other, once that is done then the transplant center must release its hold on one of the organs.

The Committee decided to put in another alternative solution in the memo that acknowledged timing issues without stipulating a specific amount of time. Their reasoning was that this would open a dialogue about the issues without locking the Committee into anything before discussions could take place.

Next steps:

- Two Committee Members and the Vice Chair will work together to draft a new alternative solution into the memo

3. Continuous Distribution: Determine Research Questions for Modeling – Medical Urgency

Presentation Summary

The Committee reviewed the following attributes under the medical urgency goal for continuing distribution.

Status 1A/1B

Purpose: Candidates listed as Status 1A receive the highest priority, followed by Status 1B

Rating Scale: Give Status 1A candidates the highest composite allocation score(CAS), followed by Status 1B candidates

MELD/PELD

Purpose: Prioritize candidates who are most likely to die/be removed from the waitlist without a transplant

Rating Scale: Map MELD/PELD score to SRTR's mortality curve and assign the proportion of medical urgency points from the Y-axis

Liver-intestine Registration

Purpose: Prioritize liver intestine candidates who are most likely to die/be removed from the waitlist without a transplant

Rating Scale: Binary Y/N and a donor modifier (BDB, BMI<=30, Age<=40, and non-diabetic candidates)

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee discussed if Status A1/B1 patients should go to the top of the urgency score or the CAS score. If they go to the top of the urgency attribute score their CAS score will be high naturally but it may not always put them at the top of the match run. If their CAS score is set high, they will always be highest on a match run. The Committee expressed concern that they did not want organs flying across the U.S when it wasn't necessary, and they were unsure which option would best limit that possibility. The Chair stated that one of the reasons for developing these research questions for Scientific Registry of Transplant Recipients (SRTR) was so the Committee could see in simulation what would happen depending on their choices.

The Committee wanted to know what percentage of organ offers under the continuous distribution system would come from outside the 500 nautical mile range for Status 1A patients. The current system limits offers for Status 1A patients to within 500 nautical miles. One member suggested asking the same question but for all patients rather than just Status 1A patients. The Chair and Vice Chair expressed support for this question.

Next steps:

The Committee will continue to discuss research questions at their next meeting.

Upcoming Meeting

- December 6, 2024,

Attendance

- **Committee Members**
 - Scott Biggins
 - Shimul Shah
 - Collen Reed
 - Tovah Dorsey-Pollard
 - Lloyd Brown
 - Joseph DiNorcia
 - Omer Junaidi
 - Michael Kriss
 - James Pomposelli
 - Vanessa Cowan
 - Christine Radolovic
 - Neil Shah
 - Aaron Ahearn
 - Vanessa Pucciarelli
 - Chris Sonnenday

- **SRTR Staff**
 - Katie Audette
 - Jack Lake
 - Nick Wood

- **UNOS Staff**
 - Emily Ward
 - Cole Fox
 - Ben Schumacher
 - Alina Martinez
 - Niyati Upadhyay
 - Keighly Bradbrook
 - Eric Messick