

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

June 10, 2022

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 06/10/2022 to discuss the following agenda items:

1. Review and Vote: Ongoing Review of National Liver Review Board (NLRB) Diagnoses
2. Review and Vote: Aligning End Dates for Liver Variances
3. Continuous Distribution: Review Plan for Attribute Presentations and Discussions

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

1. Review and Vote: Ongoing Review of National Liver Review Board (NLRB) Diagnoses

The Committee reviewed updated guidance for the *Ongoing Review of NLRB Diagnoses* proposal. The Committee voted to send the proposal to public comment in August 2022.

Summary of discussion:

The Committee reviewed the proposed recommendations from the National Liver Review Board Subcommittee (NLRB Subcommittee) for the following diagnoses familial amyloid neuropathy (FAP), cystic fibrosis (CF), hepatopulmonary syndrome, Budd Chiari, and multiple hepatic adenomas.

For the proposed guidance for multiple hepatic adenomas, a member suggested adding language to clarify that the adenoma must meet all three of the outlined criteria (unresponsive to medical management, unresectable, and progressive or with complications such a hemorrhage or malignant transformation). Members agreed with the proposed clarification.

Another member stated that only glycogen storage disease (GSD) type 1 carries the hepatocellular carcinoma (HCC) risk but that may be too nuanced to specify in guidance.

For the CF proposed guidance, the Committee will seek feedback regarding areas to shorten the guidance. A member suggested specifying that patients should have moderate to severe malnutrition. The member explained that malnutrition is significant for this population as it contributes to worsening pulmonary failure. The Chair of the Pediatric Transplantation Committee agreed.

For FAP, the Chair of the NLRB Subcommittee recommended keeping the language in OPTN policy as is. The NLRB Subcommittee will revisit this policy and propose possible modifications in the future, which may require IT implementation.

The Committee voted on the following:

- Do you support sending the proposed changes to NLRB guidance out for public comment in August 2022?
 - Support - 13, Abstain – 0, Oppose - 0

Next steps:

The proposal will be submitted for public comment. The Committee will review feedback submitted from the transplant community.

2. Review and Vote: Aligning End Dates for Liver Variances

The Committee reviewed the proposal to align the end dates of the variances in OPTN liver policy.

Summary of discussion:

The Committee proposes to align the four variances in OPTN liver policy to expire upon implementation of continuous distribution of livers and intestines.

The proposal does not change the content of any of the four variances in OPTN liver policy. The Committee will continue to monitor the variances and should data identify an issue prior to the implementation of continuous distribution, the Committee may sponsor a proposal to address the identified problem.

As the Committee develops a points-based allocation system for livers and intestines, they will consider which aspects of the variances to incorporate into permanent OPTN policy.

The Committee voted on the following:

- Do you support sending the proposed changes to the liver variance expiration dates as discussed today out for public comment in August 2022?
 - Support – 13, Abstain – 0, Oppose - 0

Next steps:

The proposal will be submitted for public comment. The Committee will review feedback submitted from the transplant community.

3. Continuous Distribution: Review Plan for Attribute Presentations and Discussions

The Committee reviewed the plan for identifying and discussing attributes for the continuous distribution of liver and intestinal organs.

Summary of discussion:

The Chair mentioned research that highlighted regions utilizing donation after cardiac death (DCD) livers show decreased number of HCC patients on the waiting list. The Chair recommended that this member present their research during the discussion of the HCC stratification attribute. A member stated that this could be included in the donor factors attribute as well.

Another member asked how MELD is being considered within the identified attributes. Staff responded that MELD is categorized as waitlist survival. Staff explained that the Committee will be reviewing attributes that are not currently a part of OPTN liver allocation, and whether or not, any of those attributes should be included in the first phase of continuous distribution.

The Vice Chair urged the inclusion of intestinal organ transplant subject matter experts for those related discussions.

A member suggested to narrow surgical complexity to those individuals waiting for a re-transplant. A member agreed.

Next steps:

Committee members will continue to sign up for specific attributes to research and present their findings during the next meeting.

Upcoming Meeting

- June 24, 2022 @ 12:00 PM ET (teleconference)
- July 8, 2022 @ 12:00 PM ET (teleconference)

Attendance

- **Committee Members**
 - Allison Kwong
 - Bailey Heiting
 - Greg McKenna
 - James Eason
 - James Markmann
 - James Trotter
 - James Pomposelli
 - Jorge Reyes
 - Kym Watt
 - Pete Abt
 - Peter Matthews
 - Scott Biggins
 - Sophoclis Alexopoulos
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Ajay Israni
 - Caitlyn Nystedt
 - John Lake
 - Nick Wood
 - Tim Weaver
- **UNOS Staff**
 - Joel Newman
 - Julia Foutz
 - Kaitlin Swanner
 - Liz Robbins
 - Matt Cafarella
 - Meghan McDermott
 - Niyati Upadhyay
 - Sarah Scott
 - Susan Tlusty
- **Other Attendees**
 - Christopher Sonnenday
 - Colleen Reed
 - Ellie Karls
 - Evelyn Hsu
 - Samantha Delair
 - Samantha Taylor
 - Sanjay Mehrotra
 - Erin Maynard
 - Neil Shah
 - Vanessa Pucciarelli