

Meeting Summary

OPTN Liver and Intestinal Organ Transplantation Committee National Liver Review Board Subcommittee Meeting Summary October 13, 2020 Conference Call

James Trotter, MD, Committee Chair James Pomposelli, MD, PhD, Committee Vice Chair Julie Heimbach, MD, Subcommittee Chair

Introduction

The National Liver Review Board (NLRB) Subcommittee (the Subcommittee) met via teleconference on 10/13/2020 to discuss the following agenda items:

- 1. Further Enhancements to the NLRB: Post-Public Comment Changes
- 2. Updating NLRB Guidance Documents and Policy Clarification

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

1. Further Enhancements to the NLRB: Post-Public Comment Changes

The Subcommittee continued discussions on post-public comment changes to the *Further Enhancements to the National Liver Review Board* proposal.

Summary of Data

The Subcommittee reviewed post-public comment changes to the following areas of the proposal:

- Portopulmonary Hypertension (POPH)
- Pediatric ART Leader
- Polycystic Liver Disease (PLD)

Portopulmonary Hypertension (POPH)

The Subcommittee reviewed feedback from the American Society for Transplant Surgeons (ASTS) related to POPH diagnostic criteria. ASTS's comments recommend changing some of the specific policy language in pre-treatment and post-treatment criteria.

The Subcommittee reviewed data from studies on POPH and concluded the data available does not support the recommended changes. The Subcommittee decided not to incorporate the suggested changes from the ASTS.

The ASTS also requested graft survival outcome data of POPH patients since 2018 and the Subcommittee will work with staff to provide this data to ASTS.

Pediatric ART Leader

The Subcommittee reviewed feedback on the proposed Pediatric ART Leader language. Based on feedback, the Subcommittee agreed to add additional language to specify the ART leader for the Adult ART will be a member of the Committee serving on either the Adult Other Diagnosis specialty board or the Adult HCC specialty board. The ART leader for the Pediatric ART will be a member of the Liver Committee or Pediatric Committee serving on the Pediatric specialty board. For both the Adult and

Pediatric ART, if there are no current members of the Liver Committee or Pediatric Committee available to serve as the ART leader, prior Committee members or other members of the NLRB can be appointed to serve as the ART leader.

Polycystic Liver Disease (PLD)

The Subcommittee then reviewed public comment feedback on proposed PLD guidance changes. Feedback suggested that "moderate to severe protein calorie malnutrition" should be more objectively defined. The Subcommittee discussed more objective measures but ultimately determined that moderate to severe protein calorie malnutrition is the most appropriate addition to the guidance.

Next Steps

The Subcommittee's recommendations for post-public comment changes will be reviewed by the full Committee in late October.

2. Updating NLRB Guidance Documents and Policy Clarification

The Subcommittee continued discussions on the upcoming proposal to update NLRB guidance documents and clarify some sections of policy. The Subcommittee revisited the discussion on updating neuroendocrine tumor (NET) guidance.

Summary of Data

Current NLRB guidance on NET includes a recommendation that the candidate be less than 60 years old.

A Subcommittee member recommended removing the age restriction from the current guidance on neuroendocrine tumors and presented data from his or her program to support the recommendation. The member also presented OPTN data which showed from 2005-2015, 125 patients were transplanted with a NET diagnosis. Twenty-five of those patients were over the age of 59 and 96 percent of those patients survived past the 1 year mark, 84 percent at three years, and 80 percent at five years.

Summary of Discussion

A Subcommittee discussed whether to remove the language specific to age and members agreed it's reasonable to remove the language. The Subcommittee requested additional data past 2015 before deciding to include the change in the proposal.

Next Steps

The recommendation will be brought to the full Committee for review in late October.

Upcoming Meetings

November 12

Attendance

• Subcommittee Members

- Kimberly Brown
- o James Eason
- o Alan Gunderson
- o Jennifer Kerney
- o Jim Markmann
- o Greg McKenna
- James Trotter

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

• UNOS Staff

- o Matt Cafarella
- o Betsy Gans
- o Lindsay Larkin
- o Leah Slife
- o Karen Williams