

OPTN Liver and Intestinal Organ Transplantation Committee National Liver Review Board Subcommittee Meeting Summary October 8, 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 10/08/2020 to discuss the following agenda items:

- 1. Updating Pediatric Guidance
- 2. Cholangiocarcinoma (CCA) Policy Update
- 3. Public Comment Review
- 4. Updating Primary Sclerosing Cholangitis (PSC) Guidance

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

1. Updating Pediatric Guidance

The Subcommittee reviewed proposed changes to the Pediatric Guidance.

Summary of Data

Representatives from the Pediatric Committee presented recommended changes to the guidance language. The proposed changes involve updating guidance for:

- Gastrointestinal bleeding
- Growth failure/nutritional insufficiency
- Metabolic liver disease
- Conclusion

Summary of Discussion

A Subcommittee member recommended adding some verbiage that notes malnutrition is a factor in poor mortality in children.

The Subcommittee supported the recommended changes.

Next Steps

The recommendations will be reviewed by the full Committee on October 22.

2. Cholangiocarcinoma (CCA) Policy Update

The Subcommittee reviewed a proposed addition to CCA criteria policy.

The Subcommittee was informed that currently, policy does not include the presence of tumor in the list of diagnostic criteria. The proposed change is to add such language to the list of diagnostic criteria for CCA.

Summary of Discussion

The Subcommittee supported the recommended change.

Next Steps

The recommendations will be reviewed by the full Committee on October 22.

3. Public Comment Review

The Subcommittee reviewed Public Comment feedback on the *Further Enhancements to the National Liver Review Board* proposal.

Summary of Data

The proposal was broadly supported across all OPTN regions. There was also overall support from stakeholder societies and committees.

As a result of public comment feedback, the Subcommittee will consider potential post-public comment changes to the following areas of the proposal:

- Portopulmonary Hypertension (POPH)
- Hepatocellular Carcinoma (HCC) explant pathology form review process
- Pediatric ART Leader
- Polycystic Liver Disease (PLD)

Summary of Discussion

The Subcommittee reviewed and considered comments submitted by the American Society of Transplant Surgeons (ASTS) on POPH criteria. The Subcommittee determined there will need to be further collaboration with ASTS representatives due to the complexity of the recommended changes.

The Subcommittee reviewed the originally proposed updates to policy language related to the HCC posttransplant explant pathology form. Based on public comment feedback, the Subcommittee changed "treatment" to "liver-directed therapy". Additionally, the Subcommittee added more explicit language specifying the Committee may refer cases to the Membership and Professional Standards Committee (MPSC) for review.

The Subcommittee then reviewed originally proposed language establishing a Pediatric ART Leader. Based on public comment feedback, the Subcommittee will add more specific language the Pediatric ART leader and the specific responsibilities of each ART leader.

Next Steps

The Subcommittee will continue discussions on post-public comment changes on the next call.

4. Updating Primary Sclerosing Cholangitis (PSC) Guidance

The Subcommittee continued discussions on updating the PSC guidance and reviewed some proposed updates based on prior discussions.

Summary of Discussion:

The Chair presented proposed guidance updates which makes the criteria for PSC exception less restrictive. The Subcommittee agreed the language should be less restrictive as proposed.

Next Steps

The Subcommittee will continue refining the proposed changes to PSC guidance on the next call.

Upcoming Meetings

- October 13
- November 12

Attendance

• Subcommittee Members

- Kimberly Brown
- o James Eason
- Alan Gunderson
- Julie Heimbach
- Jennifer Kerney
- o Jorge Reyes
- o Jim Markmann
- o Greg McKenna
- o James Pomposelli

• HRSA Representatives

- Adriana Martinez
- Jim Bowman
- o Marilyn Levi

• SRTR Representatives

- Michael Conboy
- o John Lake
- UNOS Staff
 - o Nicole Benjamin
 - Matt Cafarella
 - Betsy Gans
 - o Jennifer Musick
 - o Leah Slife
 - Victor Melendez
 - o Samantha Noreen
 - o Karen Williams

• Other Attendees

- o Emily Perito
- o Evelyn Hsu
- George Mazariegos