

Meeting Summary

OPTN Liver and Intestinal Organ Transplantation Committee National Liver Review Board Subcommittee Meeting Summary September 10, 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 09/10/2020 to discuss the following agenda items:

- 1. Project Update: Updating National Liver Review Board Guidance and Policy Clarifications
- 2. NLRB Survey Data Report
- 3. Public Comment Update and Primary Sclerosing Cholangitis (PSC) Data Report
- 4. CCA Standardized Criteria in Policy

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

1. Project Update: Updating National Liver Review Board Guidance and Policy Clarifications

The Subcommittee received an update on their proposed project to update NRLB guidance and clarify NLRB policy.

Summary of Data

The project was approved by the Policy Oversight Committee and will include:

- Changes to pediatric guidance
- Updates to primary sclerosing cholangitis (PSC) guidance
- Clarifying CCA standardized criteria
- Any additional clarifications to policy or changes to guidance

The project is planned to go to public comment in January 2021.

Next Steps

The Subcommittee will discuss more specifics regarding the project plan and timeline in future meetings.

2. NLRB Survey Data Report

The Subcommittee reviewed the NLRB Survey Data Report.

Summary of Data

The Chair highlighted some key areas of the report:

- 79 percent said guidance was useful or very useful
- ART 96 percent felt prepared for calls, and 87 percent said number of calls was right amount

- Key areas of guidance to improve:
 - o HCC specific guidance
 - Expectations for narratives
 - PCLKD: rework with "expert hepatology guidance"
 - Consolidate policy and guidance, especially for HCC
- Suggested diagnoses to include in guidance
 - o Encephalopathy was recommended multiple times in the survey

Additional key recommendations for improvement included:

- Mobile access
- Audit reviewers and provide a way for reviewers to see how others voted on cases they voted on
- Continuing education: every 6 month webinar series for reviewers and for centers
- Give alternates a chance to participate
- Direct link from where reviewing to exact place in guidance

Summary of Discussion

A member commented the current guidance is too proscriptive in some areas and may be viewed by the community as policy. Select members volunteered to review specific survey recommendations independently and come back to the Subcommittee with proposed changes.

3. Public Comment Update and Primary Sclerosing Cholangitis (PSC) Data Report

The Subcommittee received a brief Public Comment update on the *Further Enhancements to the National Liver Review Board* proposal. The Subcommittee also reviewed current guidance for PSC MELD exceptions and the requested data report.

Summary of Data

Six regional meetings have occurred and the proposal has been supported in those regions. Region 2 did recommend there should be more specific language for moderate to severe protein calorie malnutrition in PLD guidance.

The proposal has received numerous public comments related to MELD/PELD exception for retransplant and PSC. The Subcommittee reviewed current guidance for PSC MELD exceptions and the results from a data request on PSC. The data report looked at candidates on the waiting list with PSC, Waitlist removal (due to death or too sick for transplant) rates for PSC candidates compared to all liver candidates, transplant rates for PSC candidates compared to all liver candidates, and deceased donor liver transplant recipients with PSC.

Summary of Discussion

Subcommittee members commented the data report a large number of PSC candidates are removed from the Waitlist once they reach MELD 33 or higher, but they have a lower removal rate overall when compared to other liver candidates. Members also commented the data shows PSC patients with high MELD similarly have higher transplant rates when compared to other liver candidates.

The Subcommittee discussed whether the PSC guidance should be updated based on the data available. Members commented the data provided doesn't show sufficient evidence to warrant a change to the guidance for PSC exceptions. The Subcommittee requested more detail on the PSC candidate's MELD scores when they are removed from the Waitlist or transplanted.

Next Steps

The Subcommittee will gather more data and literature to continue to consider ways to update the PSC exception guidance.

4. CCA Standardized Criteria in Policy

The Subcommittee reviewed a recommendation to clarify standardized CCA criteria.

Summary of Data:

The current standardized criteria do not include presence of tumor in list of diagnostic criteria. This was in a previous version of the policy however was inadvertently removed from policy. It remained in the Regional Review Board (RRB) submission templates and when RRB migrated to NLRB, the templates went away.

Summary of Discussion:

The Subcommittee Chair proposed adding "Hilar mass, which is less than 3 cm in radial diameter (if greater than 3 cm in radial diameter, or extension into liver parenchyma, this exceeds size criteria and the patient is not eligible for standard exception)" to the current diagnostic criteria.

The Subcommittee agreed to add the criteria back into the policy and include it in an upcoming public comment proposal.

Upcoming Meetings

October 8

Attendance

• Subcommittee Members

- o Alan Gunderson
- o Julie Heimbach
- Jennifer Kerney
- Jorge Reyes
- James Trotter
- o John Lake
- o Jim Markmann
- o Greg McKenna
- o James Pomposelli
- o James Eason

• HRSA Representatives

- o Jim Bowman
- Marilyn Levi
- o Bob Walsh

UNOS Staff

- o Roger Brown
- Keighly Bradbrook
- Matt Cafarella
- o Betsy Gans
- Jennifer Musick
- o Leah Slife
- Lindsay Larkin
- o Liz Robbins Callahan
- Matthew Prentice
- Samantha Noreen
- Karen Williams