

## OPTN Liver & Intestinal Organ Transplantation Committee

### Meeting Summary

April 14, 2020

Conference Call

James Trotter, MD, Chair

James Pomposelli, MD, PhD, Vice Chair

### Introduction

The Liver & Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToTraining teleconference on 4/14/2020 to discuss the following agenda items:

1. NLRB Enhancements Part One
2. NLRB Enhancements Part Two

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

### 1. NLRB Enhancements Part One

The Committee reviewed public comment feedback on the *Enhancements to the National Liver Review Board* proposal.

#### Summary of Data

The proposal was widely supported across the OPTN regions. Themes in public comment were:

- Inactive reviewers should be removed every six months, not 12 months
- Not all adults with metabolic disease should be considered for MMat-3
- Align review board scope in policy and guidelines

The Committee then reviewed changes made to the proposal post-public comment:

- Timeframe for removing inactive reviewers
  - Original proposal:
    - *NLRB Reviewers removed if failure to vote in timely manner on more than 5% of cases within 12 months*
  - Proposed change:
    - *NLRB reviewers removed if failure to vote in timely manner on more than 5% of cases within 6 months*
- Align scope of NLRB in policy and guidelines
  - Original proposal- Operational guidelines:
    - *The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency, anticipated transplant efficacy, waitlist dropout rates, and waitlist mortality risk of the candidate.*
  - Proposed change to Operational guidelines:
    - *The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency of the candidate as compared to other candidates with the same MELD or PELD score.*
  - Additional change to Policy 9.4.A language:
    - *A MELD or PELD score exception request must include all the following:*

- *An explanation of how the candidate's current condition ~~and potential for benefit from transplant would be~~ is comparable to that of other candidates with that MELD or PELD score*
  - Clarify guidance for adults with metabolic disease
    - Original guidance:
      - *Adults who develop metabolic symptoms secondary to an inherited organic acidemia or urea cycle defect which are typically transplanted during infancy or childhood may be suitable for MELD exception. Given later onset, anticipate a reduced urgency compared to early-onset disease, thus priority for transplant may be similar to other exceptions and would recommend MMaT-3, though if a patient has more urgent medical condition, as reflected by life-threatening complications, a higher priority score can be considered.*
    - Proposed change:
      - *Adults who develop metabolic symptoms secondary to an inherited organic acidemia or urea cycle defect which are typically transplanted during infancy or childhood may be suitable for MELD exception. Given later onset, anticipate a reduced urgency compared to early-onset disease, thus priority for transplant may be similar to other exceptions ~~and would recommend MMaT-3,~~ though if a patient has more urgent medical condition, as reflected by life-threatening complications, a higher priority score can be considered.*

### Summary of Discussion

A committee member suggested there should be an effort to operationalize the follow-up with NLRB reviewers in regular intervals. The Committee then reviewed a draft of the proposed policy changes.

### VOTE

Do you support sending the enhancements to the NLRB as presented today to the OPTN Board of Directors for consideration?

- Support - 100% (17)
- Abstain - 0%
- Oppose - 0%

The vote was confirmed via a voice vote of all Committee members.

## **2. NLRB Enhancements Part Two**

The Committee reviewed and discussed proposed NLRB enhancements for summer 2020 public comment.

### Summary of Data and Discussion

The Committee reviewed proposed enhancements to the NLRB previously discussed by the group.

- Changes to guidance for PLD/PCLKD
- Creating a Pediatric ART
- Adding an ART Leader

The Committee was then presented with ideas for additional enhancements to the NLRB for discussion.

Changes to standard criteria for portopulmonary hypertension

A physician member of the community gave a presentation to the Committee on suggested policy revisions for portopulmonary hypertension MELD exception.

The presenter recommended the following revisions to POPH MELD exception policy:

- Modify pulmonary hemodynamic criteria to additionally grant exception if, with POPH treatment, PVR is less than 240 dyne.s.cm-5 and mPAP is less than 45 mmHg
- Add a free text field to the exception form that allows for entering a liver-related indication for liver transplant or echocardiogram comment

The presenter also asked the Committee to consider creating a POPH MELD exception registry and to prepare an educational effort for anesthesiologists and surgeons.

A committee member asked on a net basis, if this would result in more POPH patients being transplanted or less. The presenter thought this change would result in more transplants as it is currently restricted by policy language. Another committee member recommended instead of adding a free text option, adding a list of standard liver-related indications for transplant to select from.

The Committee will continue to evaluate these recommended changes in preparation for the next NLRB enhancements proposal.

#### Changing score for standard CCA exceptions

The Committee reviewed a data report requested by the NLRB Subcommittee on waitlist mortality, transplant, and survival data for patients with cholangiocarcinoma (CCA) exceptions compared to those with hepatocellular carcinoma (HCC) exceptions.

The report summarized the following:

- Probability of removal from the waitlist for transplant is similar for CCA and HCC candidates
- Probability of removal from the waitlist due to death or too sick for transplant is higher for CCA candidates compared to HCC candidates
- In the cohort of DD liver transplant recipients from 11/1/2015-7/31/2017: There were no statistically significant differences in post-transplant survival probabilities over a two-year period
- In the cohort of DD liver transplant recipients from 1/1/2012-7/31/2014: CCA recipients experienced lower post-transplant survival probabilities than HCC recipients over a five-year period. The difference is less evident during the first year post-transplant

In current policy, CCA exception candidates are assigned MMaT-3. The Committee discussed if this assigned score is appropriate for CCA exception candidates. The Committee expressed interest in updating this policy but would like to see more data before making a decision.

#### HCC Explant Pathology Policy Review

The Committee reviewed current policy language for HCC Explant Pathology:

- *For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the Post-Transplant Explant Pathology Form to the OPTN Contractor within 60 days of transplant. If the pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in a one-year period are not supported by the required pathologic confirmation or submission of clinical information.*

The NLRB Subcommittee has received feedback from UNOS staff that the policy for HCC Explant Pathology as written is difficult to operationalize as UNOS staff do not interpret medical information so are unable to determine when a program hits the 10 percent threshold.

The Committee was presented with the following proposed solution:

- Change policy so that a transplant hospital is reviewed by the Liver Committee if greater than 10 percent of Explant Pathology forms in a year show no evidence of HCC and no treatment of HCC
- Additional documentation is only submitted once the 10 percent threshold is met and program is being reviewed by Liver Committee

The NLRB Subcommittee Chair commented this is a simple but important change and does not change the intent of the policy.

#### Next Steps

Language will be drafted for review reflecting committee feedback. The Committee will vote on final language to send for public comment in June.

#### **Upcoming Meeting**

- May 1, 2020