

**OPTN Liver and Intestinal Transplantation Committee  
OPTN National Liver Review Board (NLRB) Subcommittee  
Meeting Summary  
April 8, 2021  
Conference Call**

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

## **Introduction**

The OPTN NLRB Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on 04/08/2021 to discuss the following agenda items:

1. Hepatocellular carcinoma (HCC) Guidance
2. Ischemic Cholangiopathy Guidance

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

### **1. Hepatocellular carcinoma (HCC) Guidance**

The Subcommittee discussed guidance related to immunotherapy, candidates beyond downstaging, and candidates with a prior history of HCC.

#### Summary of discussion:

The Subcommittee discussed adding a statement on immunotherapy to NLRB guidance. Members agreed upon adding guidance to the effect of:

“Evidence for the use of immunotherapy as a downstaging or bridging therapy is very preliminary. However, based on the published data in transplant and non-transplant setting, the use of immunotherapy does not preclude consideration for HCC.”

The Subcommittee discussed guidance for candidates beyond downstaging and if there is any evidence to support lengthening the waiting period to twelve months from the current six month requirement. A member noted that the Subcommittee should use evidence to decide if candidates beyond downstaging are as risky as candidates with ruptured HCC or primary portal branch. Some members agreed that the required waiting period for these candidates should be longer than six months. Other members preferred keeping the required waiting time at six months. The Subcommittee determined that they would need more evidence before they could come to a consensus. Members will search the literature for evidence.

The Subcommittee discussed guidance for candidates with prior history of HCC. Members were asked to clarify if candidates whose tumors were resected more than two years ago need to wait six months to receive Median MELD at Transplant (MMaT) -3. Members agreed that these candidates should not have the six month waiting period. The Subcommittee also discussed if patients who have been treated at any time and have a prolonged interval with no recurrence, but do have a new recurrence should also not have to observe the six month period. Members supported eliminating the six month waiting period for these candidates.

## **2. Ischemic Cholangiopathy Guidance**

### Summary of discussion:

Members discussed Ischemic Cholangiopathy and the recommendation for a higher exception score. A member explained that a higher score could be used as a safety net and to encourage the use of DCD donors. The Subcommittee considered moving Ischemic Cholangiopathy from guidance to policy to allow for automatic exceptions. A member noted that the exception score would need to be high enough for these patients to be retransplanted in a timely manner. Another member suggested the implementation of a waiting period before retransplantation to ensure programs with DCD transplant recipients have attempted other forms of treatment. A member reported that current guidance does not include a waiting period, but does require multiple attempts to treat the DCD transplant recipient before relisting for transplant. Members voiced their support for the addition of a minimum time to transplant. A member suggested looking at current functionality of Ischemic Cholangiopathy Guidance. The Subcommittee determined that they will need to submit a data request. A member reported that this request should utilize data from 2015 to present and include patients who have received a DCD and are relisted for transplant. This data request will include information on waiting times, mortality, and whether or not the DCD recipient had an exception request approved or denied.

### Next steps:

The Subcommittee will submit a data request to determine if any changes should be made to current Ischemic Cholangiopathy Guidance.

### **Upcoming Meetings**

- May 13, 2021

## Attendance

- **Subcommittee Members**
  - Kimberly Brown
  - James Easton
  - Julie Heimbach
  - Greg Mckenna
  - Jorge Reyes
  - James Trotter
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - John Lake
- **UNOS Staff**
  - Matt Cafarella
  - Betsy Gans
  - Jennifer Musick
  - Samantha Noreen
  - Kelley Poff
  - Matt Prentice
  - Niyati Upadhyay