

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
September 12, 2023
Conference Call**

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on 09/12/2023 to discuss the following agenda items:

1. NLRB Transplant Oncology

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

1. NLRB Transplant Oncology

The Subcommittee continued to develop the NLRB guidance language regarding intrahepatic cholangiocarcinoma and colorectal liver metastases as well as determine score recommendations for candidates with exceptions for these diagnoses.

Summary of discussion:

Decision #1: The Committee has decided to recommend a score of MMaT minus twenty for the colorectal liver metastases guidance.

Decision #2: The Committee has decided to recommend a score of MMaT minus three for the intrahepatic cholangiocarcinoma guidance.

Colorectal Liver Metastases

A member suggested that candidates with a non-standard exception for colorectal liver metastases should have a score equivalent to a MELD score of 15. The member noted that if a candidate's exception score based on median MELD at transplant (MMaT) is below MELD 15, then the system automatically sets the candidate score to MELD 15. The member stated that the highest MMaT is 35, in California. The member suggested that a score recommendation of MMaT minus 20 may allow all candidates with a non-standard exception for colorectal liver metastases to appear on match runs with MELD scores of 15.

A member agreed with using a MMaT of minus twenty, giving colorectal liver metastatic candidates a base score of fifteen. They said this is a strong approach and did not think this score recommendation was too high, which has been a concern in the past. Other members voiced their support for the score recommendation of MMaT minus 20. A member noted that having candidates with non-standard exceptions for colorectal liver metastases appearing on match runs with MELD scores of 15 would allow for more access to transplant while not disadvantaging others on the waitlist.

Another member noted that from a regional perspective, a MELD score of 15 puts candidates low on the match run on the East and West coasts. They voiced their concern about using MMaT minus twenty, as they think it will disadvantage candidates except for those with a MELD score of thirty-five and above.

Intrahepatic Cholangiocarcinoma < 2 centimeters

A member stated that this criterion is like hepatocellular carcinoma (HCC) exceptions and suggested a score recommendation of MMaT minus 3. Other members agreed. A stated that they believe this threshold is reasonable, especially since these tumors are small.

The Chair asked if there was any data on tumors larger than two centimeters but no bigger than three centimeters, as candidates with these tumors may be mistaken as having HCC tumors. A member said the substantial evidence is for tumors less than or equal to two centimeters. A member suggested that the Subcommittee urge data for tumors larger than two centimeters but smaller than three centimeters to understand the outcomes. A member mentioned that they spoke to a colleague who considers tumors that are three centimeters on a case-by-case basis. They also informed the Subcommittee about a multicenter trial that is occurring regarding this information, but they are unsure when the results will be available. The Chair stated that the Subcommittee can update guidance in the future as research evolves.

A member asked if there was any data to suggest including a carbohydrate antigen 19-9 (CA19-9) cutoff. Another member remarked that there was not much significance about the CA19-9 in these candidates, which is why they elected to leave it out.

A member said their transplant program's individual protocol uses three centimeters or less. Another member recalls that at three centimeters, the recurrence rates are much higher but encouraged the usage of data to either support or refute that claim. The Subcommittee will discuss whether to adjust the guidance to three centimeters or less at an upcoming meeting.

Unresectable Downstaged Intrahepatic Cholangiocarcinoma

Due to the inadequate evidence to support granting a MELD exception for unresectable downstaged intrahepatic cholangiocarcinoma in adult candidates, the Subcommittee has opted to not issue guidance for this diagnosis.

Next steps:

The Subcommittee will continue to work on revising the guidance document before bringing it to the larger OPTN Liver and Intestinal Organ Transplantation Committee for review.

Upcoming Meetings

- October 10, 2023 (teleconference)

Attendance

- **Committee Members**
 - Allison Kwong
 - James Pomposelli
 - Joseph DiNorcia
 - Kym Watt
 - Shimul Shah
 - Sophoclis Alexopoulos
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jack Lake
- **UNOS Staff**
 - Erin Schnellinger
 - Joel Newman
 - Katrina Gauntt
 - Kayla Balfour
 - Matt Cafarella
 - Meghan McDermott
 - Susan Tlusty