

**OPTN Liver and Intestinal Organ Transplantation Committee****Meeting Summary****June 21, 2024****Conference Call****Scott Biggins, MD, Chair****Shimul Shah, MD, MHCM, Vice Chair****Introduction**

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via WebEx teleconference on 06/21/2024 to discuss the following agenda items:

1. Continuous Distribution: Standard Exceptions
2. Member Recognition
3. Multi-organ Transplant Allocation Issue

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

**1. Continuous Distribution: Standard Exceptions**

The Committee discussed the purpose and goal alignment of each standard exception found within Policy 9.5: *Specific Standardized MELD or PELD Score Exceptions*. Defining the purpose and goal alignment will help determine how to incorporate each standard exception within the continuous distribution framework. The Committee provided pre-meeting input on which goal(s) of continuous distribution they thought each exception aligned with.

Summary of discussion:*Hepatocellular Carcinoma (HCC)*

The Chair stated that the majority of members indicated that patient access was the primary goal of standard exception for HCC. The Chair noted that there was additional alignment with both medical urgency as well as post-transplant survival. A member mentioned that points for HCC exceptions may not need to align with the goal of post-transplant survival but rather the criteria in Policy 9.5.I: *Requirements for HCC MELD or PELD Score Exceptions* that addresses post-transplant survival factors which should be maintained in a continuous distribution system.

Another member stated that the HCC exception may align with the goal of biologic disadvantage because they cannot control the cancer and may not be as sick as other candidates on the waitlist.

Based on last the discussion from the previous Committee meeting as well as the pre-meeting input provided, the Chair summarized that the Committee aligns the HCC exception goal with patient access while still emphasizing some alignment with the medical urgency goal as well. Members agreed.

*Hilar Cholangiocarcinoma*

The Chair suggested that the goal alignment for hilar cholangiocarcinoma is likely similar to HCC. A member asked whether there is data regarding the rate of dropout for candidates with hilar cholangiocarcinoma compared to HCC. The member stated that there may be less of an emphasis on

medical urgency for hilar cholangiocarcinoma compared to HCC. Another member responded that the drop out rates may be appropriate because those candidates may not be suitable for transplant based on the progression of the cancer. A member agreed and reasoned that this may be the rationale for why hilar cholangiocarcinoma aligns more closely with patient access. The Vice Chair added additional rationale, stating that it is important for these candidates to receive a transplant within six weeks of receiving radiation.

#### *Cystic Fibrosis*

A member noted that the population of candidates with cystic fibrosis are heterogenous which makes determining a goal alignment difficult.

Another member stated that there is a post-transplant survival component because this population can develop untreatable bacteria so giving them more access to transplant may affect post-transplant survival. The Chair stated that perhaps the criteria should be updated to address situations where there is a multi-drug resistant organism. The member agreed that the criteria may need to be updated rather than aligning the exception with the goal of post-transplant survival.

A member stated that these candidates need access to higher quality organs as well. The Chair noted that this aligns more closely with the concept of donor modifiers rather than determining the purpose of the exception.

The Chair summarized that the Committee appears to agree that the main goal of the cystic fibrosis exception is patient access with acknowledgement to some medical urgency aspects.

#### *Familial Amyloid Polyneuropathy (FAP)*

The Chair stated that this candidate population needs to receive a transplant before they get too sick which they believe aligns more closely with the goal of patient access. An SRTR representative noted that candidates who have access to a domino donor liver could receive additional patient access points. The Chair noted that the pre-meeting input provided by members was split between the goals of medical urgency and patient access.

#### *Hepatic Artery Thrombosis (HAT)*

The Chair noted that the majority of pre-meeting input from members indicated that the exception for HAT aligns the goal of medical urgency. Members agreed.

The Chair reminded the Committee that there had been prior discussions for expanding the timeframe in which a standard exception for HAT could be submitted. A member noted that early HAT is a medical urgency issue while late HAT is more of a patient access issue.

#### *Hepatopulmonary Syndrome*

A member noted that the biggest concern with this population is ensuring post-transplant survival and having access to a higher quality organ is important in that consideration. The member stated that this means that this candidate population needs more access in order to receive offers of higher quality. The Chair stated that this may require a donor modification. Another member responded that it depends on the severity of the disease.

The Chair summarized that there are areas of patient access and medical urgency for this exception, but it appears to align more closely with patient access.

### *Metabolic Disease*

The Chair noted that the majority of pre-meeting input from members indicated a split between patient access and medical urgency.

### *Portopulmonary Hypertension*

The Vice Chair wondered if the rationale for the purpose of the portopulmonary hypertension exception should be the same as the rationale for the hepatopulmonary syndrome exception. A member responded that one could argue that the rationale could be different as portopulmonary hypertension requires a lot more therapies and is a harder disease to keep stable than hepatopulmonary syndrome. Another member stated that this candidate population has cardiopulmonary urgency.

A member stated that it is not common for candidates with portopulmonary hypertension to not be able to receive treatment because their liver is too sick. The Chair indicated that that rationale aligns more with patient access than medical urgency.

### *Primary Hyperoxaluria*

The Chair noted that this exception may align more closely with patient access due to the policy currently stating that candidates meeting these criteria receive median MELD at transplant (MMaT).

#### Next steps:

The Committee will continue to discuss this topic in the context of liver continuous distribution.

## **2. Member Recognition**

The Committee recognized members whose terms have ended and thanked them for their service.

## **3. Multi-organ Transplant Allocation Issue**

The Vice Chair brought forward a recent multi-organ transplant allocation issue.

#### Summary of discussion:

The Vice Chair noted their experience, as well as experience from other liver colleagues that lung-liver combinations are usurping liver-alone offers for high MELD and Status 1A/1B candidates on the match run. The Vice Chair noted that they are not sure the exact cause of this issue but emphasized that MELD 40 and Status 1A/1B candidates should have priority for offers.

A member stated that OPOs have to make multi-organ combination offers down to candidates with composite allocation scores (CAS) of 25 for lung before submitting other offers. The member explained that this may mean that the OPO is making around 200 lung offers to find a primary recipient before offering the liver-alone, if there is a multi-organ. The member stated that this is a general issue across multi-organ allocation and a topic under review by the OPTN Ad Hoc Multi-Organ Transplantation Committee.

Another member noted their concern with OPOs offering organs outside of match runs.

An SRTR representative stated that the Ad Hoc Multi-Organ Transplantation Committee should review these issues and determine solutions by utilizing a single medical acuity metric to understand waitlist mortality across organs.

#### Next steps:

The Committee will relay this allocation issue to the OPTN Ad Hoc Multi-Organ Transplantation Committee and ensure there is Committee representation within these discussions.

## **Upcoming Meetings**

- July 19, 2024 at 2 pm ET (teleconference)

## Attendance

- **Committee Members**
  - Aaron Ahearn
  - Allison Kwong
  - Chris Sonnenday
  - Christine Radolovic
  - Colleen Reed
  - Jennifer Muriett
  - Jim Pomposelli
  - Joseph DiNorcia
  - Kathy Campbell
  - Kym Watt
  - Lloyd Brown
  - Neil Shah
  - Omer Junaidi
  - Scott Biggins
  - Shimul Shah
  - Tovah Dorsey-Pollard
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jack Lake
  - Katie Audette
  - Ryo Hirose
- **UNOS Staff**
  - Cole Fox
  - Kayla Balfour
  - Niyati Upadhyay
  - Susan Tlusty