

OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary June 7, 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 06/07/2024 to discuss the following agenda items:

- 1. Continuous Distribution: Hepatocellular Carcinoma (HCC) Stratification Attribute
- 2. Continuous Distribution: Other Standard Exceptions

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

1. Continuous Distribution: Hepatocellular Carcinoma (HCC) Stratification Attribute

The Committee discussed the purpose and goal alignment of HCC. The Committee provided pre-meeting input to help initiate discussions.

Summary of discussion:

No decisions were made regarding this agenda item.

The Vice Chair stated that they were interested to see that post-transplant survival was important when thinking about candidates with cancer, but that post-transplant survival is not currently included as an attribute in the liver continuous distribution framework. The Chair responded that there are guardrails in policy to ensure that post-transplant survival is accounted for in relation to some standard exceptions.

The Vice Chair stated that they believe the purpose of the HCC exception aligns with medical urgency because it depends on the risk of waitlist dropout combined with the need for transplant. The Vice Chair explained that there is an urgency for transplant based on the progression of the cancer. The Chair responded that ensuring a candidate with HCC receives a transplant before their cancer progresses is more of an access issue. The Chair added that waitlist dropout can still be addressed by providing additional points in the goal of patient access.

One member argued that this falls under the medical urgency goal, as this population needs a transplant since they are at risk of waitlist dropout because their cancer progresses, not because of liver failure. The Chair countered that argument by saying that all candidates will have medical urgency points, through their model for end-stage liver disease (MELD) score.

One member pointed out that by stratifying candidates with HCC, they have already made the argument that the purpose of the HCC exception is that of medical urgency as it implies some candidates are more medically urgent than others. A member pointed out that waitlist dropout could also be caused by the necessity of being medically removed (i.e., too sick for transplant) and so they believe there is both a medical urgency component, as well as a patient access component.

Another member stated that there is an access component for all candidates with HCC but based on the progression of the cancer, some candidates with HCC are more urgently need a transplant. The Chair noted that candidates with HCC can be stratified within the goal of patient access or medical urgency.

A HRSA representative commented that a perfect MELD algorithm would incorporate HCC and stratify it within the score, which would eliminate the need for exception points. A member stated that dropout is not for the same reason nor the same rate as the candidates with lab MELD scores that it is for candidates with an HCC exception. The member explained that candidates with HCC would not be receiving the points they need to access transplant if allocation was based fully on short-term waitlist death or drop out.

When looking at the goal of post-transplant survival, one member indicated that points are based on guardrails, and therefore post-transplant survival has already been addressed. Another member agreed and added that the criteria will likely change in the future so keeping it in policy as indications for transplant will be easier to modify rather than adjusting the guardrails based on points.

Next steps:

The Committee will continue this discussion at their next meeting.

2. Continuous Distribution: Other Standard Exceptions

The Committee discussed how to potentially incorporate exceptions for the 9 other standard diagnoses within liver continuous distribution by determining the purpose and goal alignment of each diagnosis.

Summary of discussion:

No decisions were made regarding this agenda item.

Hilar Cholangiocarcinoma

The Chair stated that the rationale for goal alignment for hilar cholangiocarcinoma will likely be similar to that of HCC once the Committee decides. One member commented that they felt this is more of a patient access issue rather than a medical urgency issue, adding that if these individuals never get access, they will never be transplanted. The member explained that candidates with hilar cholangiocarcinoma exceptions are not as likely to die or dop off the waitlist in the same way as candidates with HCC exceptions because of differences in disease progression. Another member stated that candidates with hilar cholangiocarcinoma do drop off the waitlist, so there is a medical urgency component as well as patient access.

The Vice Chair noted that preventing dropout is difficult, as candidates with hilar cholangiocarcinoma experience high incidences of recurrence post-transplant, thus using dropout as a metric is difficult, as they may not have been successful with transplant anyway so dropout may not be as indicative as one may believe.

A member noted that placement efficiency should be considered. The member explained that for some standard exception candidates, a medically complex liver offer may be appropriate for transplant, therefore, to increase efficiency, those candidates and offers should be prioritized.

Next steps:

The Committee will continue this discussion at an upcoming meeting.

Upcoming Meetings

- June 21, 2024, at 2 pm ET (teleconference)
- July 19, 2024, at 2 pm ET (teleconference)

Attendance

• Committee Members

- o Scott Biggins
- o Shimul Shah
- o Aaron Ahearn
- o Allison Kwong
- Christine Radolovic
- o Colleen Reed
- o Erin Maynard
- o Joseph DiNorcia
- o Kym Watt
- o Neil Shah
- o Omer Junaidi
- o Shunji Nagai
- Tovah Dorsey-Pollard
- o Vanessa Cowan
- o Vanessa Pucciarelli
- HRSA Representatives
 - o Jim Bowman
 - o Marilyn Levi
- SRTR Staff
 - o Jack Lake
 - o Katie Audette
- UNOS Staff
 - o Alex Carmack
 - o Cole Fox
 - o James Alcorn
 - o Katrina Gauntt
 - Kayla Balfour
 - o Meghan McDermott
 - Niyati Upadhyay
- Other
 - Emily Perito (Chair of the OPTN Pediatric Transplantation Committee)