

## **OPTN Liver and Intestinal Organ Transplantation Committee**

### **Meeting Summary**

**November 3, 2023**

**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 11/03/2023 to discuss the following agenda items:

1. Update on Correction Made to Automated Approval Process for Certain Hepatocellular Carcinoma (HCC) Exception Candidates
2. National Liver Review Board (NLRB) Transplant Oncology Project

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

### **1. Update on Correction Made to Automated Approval Process for Certain Hepatocellular Carcinoma (HCC) Exception Candidates**

The Committee received an update on the correction made to the automated approval process for certain HCC exception candidates.

#### Summary of discussion:

There were no questions or comments on this item.

### **2. National Liver Review Board (NLRB) Transplant Oncology Project**

The Committee continued to review the drafted guidance and discuss Adult HCC Review Board changes.

#### Data summary:

Oncology exception requests reviewed by the NLRB by Year Submitted and Diagnosis:

- 2020 (105 total forms)
  - Hepatic Adenoma: 10
  - Hepatic Epithelioid Hemangioendothelioma: 19
  - Hilar CCA: 39
  - Neuroendocrine Tumors: 37
- 2021 (125 total forms)
  - Hepatic Adenoma: 24
  - Hepatic Epithelioid Hemangioendothelioma: 19
  - Hilar CCA: 48
  - Neuroendocrine Tumors: 34
- 2022 (93 total forms)
  - Hepatic Adenoma: 33
  - Hepatic Epithelioid Hemangioendothelioma: 22

- Hilar CCA: 17
- Neuroendocrine Tumors: 21

#### Summary of discussion:

The Committee discussed expanding the scope of the Adult HCC Review Board to become an Adult Transplant Oncology Review Board to ensure that reviewers with the appropriate expertise are reviewing non-standard exception requests related to liver cancers and tumors. This Vice Chair suggested that an Adult Transplant Oncology Review Board should review non-standard exception cases related to colorectal liver metastases, intrahepatic cholangiocarcinoma, hepatic adenomas, neuroendocrine tumors, hepatic epithelioid hemangioendothelioma (HEHE), HCC, hilar CCA, and any other liver cancer or tumor. A member voiced their support and stated that they are not concerned about an increased amount of non-standard exception cases that an Adult Transplant Oncology Review Board would review.

Another member noted their support. The member suggested that if there is opposition to the volume of cases this Review Board will see, non-standard exception requests for hepatic adenomas could remain within the purview of the Adult Other Diagnosis Review Board.

The Vice Chair expressed their surprise at the high volume of HCC non-standard exception requests in comparison to other diagnoses. The Chair agreed, noting that the Adult HCC Review Board is often busy, but feels that expanding the role of the current Adult HCC Review Board would allow the experts in the field to review relevant non-standard exception requests. A member suggested that the Committee should review how many HCC non-standard exception requests are approved to see if there is opportunity to increase automatic approvals. The member explained that although expanding the scope of the Adult HCC Review Board may be more work for reviewers, they do not think that is a reason for not having an Adult Transplant Oncology Review Board. The member explained that developing an Adult Transplant Oncology Review Board is the right action to take to ensure reviewers with the appropriate expertise are reviewing the relevant non-standard exception requests. The Vice Chair shared earlier sentiments about tracking data and expressed that it will be an important aspect of the proposed changes.

The Chair of the OPTN Pediatric Transplantation Committee voiced their agreement to keep all the pediatric non-standard exception requests related to liver cancer and tumors with the Pediatric Review Board since these reviewers are experts in the pediatric field. They continued, expressing their desire to potentially improve guidance surrounding transplant oncology non-standard exceptions for pediatric candidates, which would be a separate effort but would appreciate the Committee's input.

An SRTR representative suggested developing templates for transplant programs to submit justification narratives in order to collect some data. The Vice Chair agreed that it would be a good idea. The Chair of the OPTN Pediatric Transplantation committee emphasized how helpful a template may be in order to review non-standard exceptions retrospectively. A HRSA representative commented that at some point, the Committee may seek to develop a project to make some non-standard exceptions more automated.

#### *System Impact*

The Committee reviewed how modifications to the Adult HCC Review Board to become an Adult Transplant Oncology Review Board would impact the system.

The Vice Chair pointed out that distal cholangiocarcinoma (dCCA) should not be sent to the Adult Transplant Oncology Review Board, as it is not an indication for transplant. The Chair countered that some candidates have had cirrhosis or an extenuating circumstance that is an indication for transplant,

but they also have a dCCA. They continued, saying that it is important to have a pathway for these candidates, but it should also be clear that a dCCA alone is not an indication for transplant.

The Vice Chair supported adding the word “unresectable” for both colorectal liver metastases and intrahepatic cholangiocarcinoma to the response options in the system as they feel it is important to stress the indication for transplant. They did mention that it was listed in the document elsewhere but felt that having it having “unresectable” in the heading would be helpful. A member expressed concern that it was redundant.

The Vice Chair voiced their concern that coordinators may have difficulty finding HEHE in the system, since they may not know that this diagnosis, among others, falls under the “other cancer or tumor diagnosis, specify” category. A member questioned if there would be a mechanism for the Adult Other Review Board to re-refer a case if necessary. They elaborated, noting that sometimes exception requests may be sent to the incorrect Review Board, and suggested having a mechanism to reroute that to the correct Review Board. The Chair advocated for listing the diagnoses as separate response options and leaving the “other cancer or tumor diagnosis, specify” field, and having those entries forwarded to the Transplant Oncology Board. The Vice Chair voiced their support for that change. A member agreed, noting that this allows the programming to be more streamlined.

The Chair explained that if the Committee approves this, then the OPTN Policy Oversight Committee (POC) will need to support the Committee’s decision to use the previously approved resource estimate to implement an Adult Transplant Oncology Review Board. The Chair reminded the Committee that POC previously approved resource estimates related to implementing contrast-enhanced ultrasound (CEUS) as an acceptable adjunct diagnostic tool for HCC. They continued, saying that updates related to CEUS will be developed for a future public comment proposal.

A member voiced their preference for removing the word “transplant” from the Adult Transplant Oncology Review Board. The Chair indicated that it is important to have the word “transplant”, as transplant oncology is different than medical oncology. The Vice Chair agreed, noting that transplant oncology is becoming its own field.

A member questioned why some HCC non-standard exception cases do not meet the standard auto-approval criteria. The Vice Chair agreed that it would be helpful to understand why some candidates are not in the auto-approval category. An SRTR representative commented that the Committee would have to look at the cases that were reviewed by the Review Board. The Vice Chair advised broadening the standard criteria so that more HCC cases are auto approved and fewer are being reviewed by the NLRB. A member mentioned that they would ask colleagues on the HCC Review Board what their experience has been, including the level of work, as well as getting their perspective on the reasoning behind the non-standard exception HCC cases.

#### *Review Guidance*

The Vice Chair encouraged the Committee to review the modifications to the Adult Transplant Oncology guidance document, the Adult MELD Exception Review guidance document, and the NLRB Operational Guidelines. They requested that the Committee be cognizant of any inconsistencies they may find in the language and send any edits and feedback in order to finalize the proposal.

The Chair reminded the Committee of the importance of attending the November 17<sup>th</sup> meeting, as a quorum is needed to vote on the guidance.

#### Next steps:

The Committee will vote to submit the project to winter 2024 public comment period during the upcoming November 17<sup>th</sup> Committee meeting.

**Upcoming Meetings**

- November 17, 2023 @ 2 pm ET (teleconference)
- December 1, 2023 @ 2 pm ET (teleconference)
- December 15, 2023 @ 2 pm ET (teleconference)

## Attendance

- **Committee Members**
  - Allison Kwong
  - Cal Matsumoto
  - Christine Radolovic
  - James Pomposelli
  - Jennifer Muriett
  - Joseph DiNorcia
  - Kym Watt
  - Lloyd Brown
  - Neil Shah
  - Scott Biggins
  - Shimul Shah
  - Sophoclis Alexopoulos
  - Tovah Dorsey-Pollard
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jack Lake
  - Katie Audette
  - Ryo Hirose
  - Tim Weaver
- **UNOS Staff**
  - Betsy Gans
  - Bonnie Felice
  - Cole Fox
  - Darby Harris
  - Erin Schnellinger
  - Joel Newman
  - Katrina Gauntt
  - Kayla Balfour
  - Meghan McDermott
  - Rob McTier
  - Susan Tlusty
- **Other**
  - David Weimer
  - Emily Perito
  - Jen Lau (visiting board member)
  - S. DeLair
  - Samantha Taylor