OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
Meeting Summary
August 8, 2023
Conference Call

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 08/08/2023 to discuss the following agenda items:

1. National Liver Review Board (NLRB) Transplant Oncology

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

1. National Liver Review Board (NLRB) Transplant Oncology

The Subcommittee received an update on the drafting of the policy and guidance language to incorporate contrast-enhanced ultrasound as an acceptable diagnostic tool for hepatocellular carcinoma. The Subcommittee also discussed adding language to *Policy 9.5.A: Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions* to specify that CCA standardized exceptions require approval of the protocol. The Subcommittee began drafting guidance for the three potential diagnoses to add to NLRB guidance: Unresectable colorectal liver metastases, unresectable intrahepatic cholangiocarcinoma $\leq$ 2 cm, and unresectable downstaged intrahepatic cholangiocarcinoma.

Summary of discussion:

Policy 9.5.A: Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A member suggested clarifying the language in the policy to specify that it is hilar cholangiocarcinoma. Other members agreed.

Another member noted that the potential need to develop policy for colorectal liver metases similar to that of hilar cholangiocarcinoma. A member agreed and reminded the Subcommittee of previous discussions in which the Subcommittee decided to develop guidance due to the lack of data currently available.

A member stated that the original intent of Policy 9.5.A was to require submission and approval of a CCA protocol. The member noted that adding in language to clarify that approval is required aligns with the intent of the policy. The Subcommittee agreed with this clarification.

Guidance Document Drafting

The Subcommittee reviewed an initial draft of guidance for the three diagnoses.

Unresectable colorectal liver metases

A member noted that their transplant program requires a one-year waiting period from time of diagnosis to time of listing. The member added that some transplant programs require a six-month waiting period. The member stated that if the guidance is stricter, then there is more of an ability to control what is happening and the results. Another member stated that the original guidelines from Oslo

recommended a two-year waiting period, and then reduced it to a one-year waiting period. Other members agreed that a one-year waiting period is appropriate.

A member clarified that time from diagnosis indicates the point in time when a candidate has a colonoscopy or biopsy, not initial treatment or resection. Another member agreed.

A member asked whether the point under *primary diagnosis* of "RAS mutations considered if other favorable biological present factors" needs to be clarified. Another member suggested removing this sentence as MSI stable is a more important and clear indication. A member agreed.

Another member asked if a right-sided cancer was different than a left-sided cancer. A member responded that right-sided cancer may have a poor prognosis but it is not a rule-out.

Another member suggested removing language the specifies guidance for circumferential negative margins as that information may not be known. Other members agreed.

A member agreed with the guidance including criterion that a PET scan is needed for evaluating extrahepatic disease. Another member stated that the guidance could be worded to indicate that a PET scan or a diagnostic tool of similar equivalence is needed to rule out metastatic disease to incorporate situations where a transplant program does not have a PET scan. The member expressed concern with how individuals would be assessing nodal disease.

A member noted that stability or regression of disease with systemic and/or locoregional therapy is a very important aspect of the evaluation of hepatic disease and prior systemic/liver directed treatment. Another member stated that there should be a timeframe associated with this part of the guidance. Members agreed that indicating three months of stability seems reasonable.

A member asked whether the guidance needs to specify that the candidate is receiving maintenance chemotherapy. Another member responded that there may be instances where the transplant and oncology teams decide that the candidate does not need continued chemotherapy due to disease stability or other reasons. The member added that the guidance may not need to be that prescriptive.

A member stated that the guidance should specify that a candidate may be eligible for an exception if they have received chemotherapy or if they are continuing to receive chemotherapy. Another member suggested clarifying the guidance to state that chemotherapy or immunotherapy are both acceptable as there are differences between the two.

The Subcommittee discussed whether to include guidance that states a colectomy should be performed within a certain time period as part of the management for synchronous disease. A member suggested this point could be clarified earlier in the guidance.

The Subcommittee reviewed potential exclusion criteria in the drafted guidance. Members agreed that detailing exclusion criteria is helpful guidance.

The Subcommittee agreed that guidance for exception extension should be included. Another member asked whether a PET scan is needed for exception extension. A member responded that it may not be necessary to include PET scan as an extension criteria, but the important criteria is to make sure there is no extrahepatic disease. Another member suggested including a negative colonoscopy within a year as an exception extension criterion. Members agreed.

Intrahepatic Cholangiocarcinoma $\leq$ 2cm

A member suggested that the guidance should include language that specifies candidates should be treated and stable for six-months. The member stated this criteria is established in the literature. Members agreed.

Another member stated that the guidance should specify that candidates should have presence of cirrhosis.

A member suggested including guidance for exception extensions.

Unresectable Downstaged Intrahepatic Cholangiocarcinoma

A member stated that this diagnosis is not ready to be included in NLRB guidance for MELD exceptions due to the lack of data. Other members agreed.

A member requested the Subcommittee to share the initial draft of guidance with their colleagues in order to gather more input. Another member agreed and emphasized it will be important to receive input from oncologists on the language.

Next steps:

The Subcommittee will continue to develop guidance and determine a score recommendation for each diagnosis.

Upcoming Meeting

- September 12, 2023 @ 2:00 PM ET (teleconference)

Attendance

- **Subcommittee Members**
  - Chris Sonnenday
  - Allison Kwong
  - Dev Desai
  - Jospeh DiNorcia
  - Kym Watt
  - Scott Biggins
  - Shimul Shah
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Representatives**
  - Jack Lake
  - Katie Audette
  - Simon Horslen
- **UNOS Staff**
  - Erin Schnellinger
  - Joel Newman
  - Kayla Balfour
  - Katrina Gauntt
  - Matt Cafarella
  - Meghan McDermott
  - Niyati Upadhyay