OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
April 5, 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 04/05/2024 to discuss the following agenda items:

1. MELD 3.0 3-month Monitoring Report
2. Public Comment Review: National Liver Review Board (NLRB) Updates Related to Transplant Oncology

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

1. MELD 3.0 3-month Monitoring Report

The Committee reviewed the three-monitoring monitoring report for the implementation of their project *Improving Liver Allocation: MELD, PELD, Status 1A, and Status 1B.*

Data summary:

MELD 3.0 key results:

- Deceased donor transplant was the most common reason for removal from the waiting list among liver candidates aged 12 years and older at removal. The proportion of females removed for deceased donor transplant increased pre- to post-policy.
- There were no statistically significant changes in waiting list removal rates due to death or too sick pre- to post-policy.
- Overall transplant rates significantly increased post-policy. When examined by sex, the transplant rate for females increased significantly pre- to post-policy, whereas the transplant rate for males remained roughly the same pre- to post-policy.
- The number and proportion of Status 1A/1B transplant recipients decreased slightly pre- to post-policy for both female and male transplant recipients. Within each sex, the median allocation MELD score at transplant remained the same pre- to post-policy, although it was higher for females compared to males.

PELD Cr key results:

- Deceased donor transplant was the most common reason for removal from the waiting list among liver candidates aged 0-11 years at removal.
- There were no statistically significant changes in transplant rates and waiting list removal rates due to death or too sick pre- to post-policy.
- The number and proportion of Status 1A/1B transplant recipients decreased pre- to post-policy. The median PELD score at transplant remained the same across policy eras, but the interquartile

range, which captures the middle 50% of PELD scores at transplant, decreased pre- to post-policy.

Status 1A/1B key results:

- Deceased donor transplant was the most common reason for removal from the waiting list among pediatric (age <18 years at removal) liver candidates with Status 1A or 1B, both overall and by diagnosis (chronic liver disease, hepatoblastoma, metabolic disease, other).
- The number of pediatric Status 1A and 1B liver transplants decreased pre- to post-policy, both overall and by diagnosis.
- Recipients with chronic liver disease made up the largest proportion of transplants, followed by metabolic disease, hepatoblastoma, and other diagnosis.
- The number of pediatric Status 1B cases that did not meet standard criteria decreased pre- to post-policy, and the number of those cases that were not approved decreased as well.

Summary of discussion:

Members expressed encouragement as the initial results indicate that some of the major goals of the project were achieved. Members were eager to review the six-month monitoring report as it will be more substantial data.

Members requested upcoming monitoring reports include body surface area (BSA) measurements in metrics.

Next steps:

The Committee will continue to monitor the impact of these policy changes.

2. Public Comment Review: National Liver Review Board (NLRB) Updates Related to Transplant Oncology

The Committee reviewed public comment received on their *NLRB Updates Related to Transplant Oncology* proposal and discussed whether any post-public comment changes are necessary.

Summary of discussion:

NLRB Guidance for Colorectal Liver Metastases

The Vice Chair noted that the American Society of Transplantation suggested that the guidance for colorectal liver metastases should include all guidance from the International Hepato-Pancreato Bilary Association (IHPBA) or explain the rationale for excluding certain aspects. The Vice Chair stated that most of the IHPBA guidance is included in the drafted NLRB guidance and would be concerned about making the guidance too prescriptive. A member asked what part of IHPBA guidance is missing from the drafted NLRB guidance. The Vice Chair stated that most of the IHBPA guidelines are incorporated but the IHPBA provide more detail while the NLRB guidance is more broad.

The Vice Chair noted that there was some public comment feedback that suggested the guidance should clarify the definition of unresectable. The Vice Chair did not agree with this suggestion as guidance should not be that prescriptive since there is transplant program variation in what is deemed to be unresectable versus respectable. Members agreed. The Chair noted that HCC policy and guidance does also not define resectable or unresectable. The Chair stated it would not be consistent to define these terms some places but not others and suggested that there either needs to be an overarching definition for all diagnoses or the guidance remain broad to allow for variation in practice. Another member stated that there is nuance with colorectal liver metastases compared to other diagnoses in terms of unresectability.

The Committee discussed public comment feedback that suggested to increase the score recommendation for colorectal liver metastases candidates. A member stated that it is difficult to have a rationale to increase the score recommendation when there is still incoming data on post-transplant survival and current data suggests that a majority of the population may not have as high survival post-transplant compared to those with chronic liver disease. The member stated that the Committee also has to consider the other populations on the waitlist. A member responded that indications for liver transplantation are expanding and populations are changing.

Another member noted that this becomes a circular argument because if this population does not have meaningful access to transplant then it becomes difficult to generate any data to justify transplant. The member stated it becomes hard to advance the field without meaningful access. A member responded that the creation of this guidance would result in more MELD points for this population than they are currently receiving. The member added that MMaT – 20 seems to be a compromise between the parts of the community that support no additional points and the other parts of the community that are advocating for more points.

A member stated that more education on what the score recommendation of MMaT – 20 means would be beneficial for the community. The member stated that raising the score recommendation and having candidates with colorectal liver metastases compete with more medical urgent candidates is more concerning than creating guidance with a low score recommendation.

Other members agreed that education will be important if this guidance is approved to ensure the community understands the rationale and impact of MMaT – 20.

The Vice Chair stated that the score recommendation of MMaT – 20 is a good compromise for now. The Vice Chair stated that the Committee can continue to review the data and adjust the score recommendation at a future point if it is justified.

A member asked whether the Committee thought the development and potential implementation of this NLRB guidance was too premature. The member stated that they are supportive of the guidance and do not believe it is too early for incorporation but noted there was some public comment feedback with this sentiment. The Chair and other members noted their support for the NLRB guidance for colorectal liver metastases.

The Chair noted that if this NLRB guidance is implemented, it may spur payors to recognize that colorectal liver metastases is an indication for transplant resulting in coverage for both live donor and deceased donor transplant which will help move the field forward.

NLRB Guidance for Intrahepatic Cholangiocarcinoma

The Vice Chair noted that there were a couple suggestions to reconsider the score recommendation for intrahepatic cholangiocarcinoma but that the majority of public comment was supportive of MMaT – 3.

The Vice Chair noted there was some public comment feedback that did not agree with the criteria for a biopsy. The Vice Chair stated that obtaining a biopsy is important in order to document and ensure that the treatment is for cholangiocarcinoma. A member agreed and stated feedback from their oncology colleagues also agreed with having biopsy be a criterion in the guidance. Other members agreed. Another member noted that if there are difficulties with obtaining a biopsy due to size then the transplant program can note that in the justification narrative.

The Vice Chair noted additional public feedback requesting clarification on the criteria related to six-months of waiting prior to submitting an exception. The Vice Chair stated that the original rationale for including the six-month time period was based on literature that analyzed intentional transplant for

intrahepatic cholangiocarcinoma where there was a six-month wait period. A member noted that there is no data regarding not waiting six months and there is a little bit of data on waiting six months.

The Committee discussed whether the six month waiting period should be applied as it is for HCC, meaning that the candidate would have to wait six months before receiving the exception points. A member noted there may be a benefit in terms of documentation and data collection if this wait period is applied to intrahepatic cholangiocarcinoma exceptions. Another member responded that implementing this alongside with guidance would be difficult as the proposal is for NLRB guidance for non-standard exceptions where information is provided via a justification narrative.

Next steps:

The Committee will continue finalizing the proposal.

Upcoming Meetings

- April 15, 2024, at 12 pm ET (teleconference)
- April 19, 2024 at 2 pm ET (teleconference)

Attendance

- **Committee Members**
  - Allison Kwong
  - Christine Radolovic
  - Chris Sonnenday
  - Colleen Reed
  - Joseph DiNorcia
  - Kathy Campbell
  - Kym Watt
  - Lloyd Brown
  - Omer Junaidi
  - Scott Biggins
  - Shimul Shah
  - Sophoclis Alexopoulos
  - Tovah Dorsey-Pollard
  - Vanessa Cowan
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Shannon Dunne
- **SRTR Staff**
  - Jack Lake
  - Katie Audette
  - Nick Wood
  - Ryo Hirose
- **UNOS Staff**
  - Cole Fox
  - Erin Schnellinger
  - Katrina Gauntt
  - Kayla Balfour
  - Laura Schmitt
  - Megan Oley
  - Meghan McDermott
  - Susan Tlusty
- **Other**
  - Jen Lau (visiting board member)