

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee**

March 12, 2024

Conference Call

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 03/12/2024 to discuss the following agenda items:

1. Refining Project Scope

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

1. Refining Project Scope

The Subcommittee reviewed and discussed which liver diagnoses to prioritize when evaluating different exception score recommendations for NLRB guidance.

Summary of discussion:

Decision #1: The Subcommittee determined the following diagnoses to prioritize reviewing and potentially changing the score recommendations: Budd Chiari, hepatic epithelioid hemangioendothelioma, hepatic hydrothorax, hepatic hemorrhagic telangiectasia, hepatic adenomas, neuroendocrine tumors, portopulmonary hypertension, primary sclerosing cholangitis/secondary sclerosing cholangitis, metabolic disease, small for size syndrome, diffuse ischemic cholangiopathy, and late vascular complications.

Decision #2: The Subcommittee decided that the following diagnoses do not need to have their score recommendations reviewed and changed at this time: ascites, gastrointestinal bleeding, hepatic encephalopathy, polycystic liver disease, multi-visceral transplant, chronic rejection, and pruritis.

The Subcommittee reviewed each of the following diagnoses. Members provided input via a survey on whether or not the score recommendation needs to be updated and what score they believe should be given with each diagnosis. This meeting allowed Subcommittee members to review the feedback compiled as well as the opportunity to provide additional comments and rationale for their decision. Although the Subcommittee opted not to update some of the score recommendations, each of the following diagnoses was discussed at the meeting:

Ascites

A member noted that removing the guidance for ascites would likely cause confusion for reviewers, thus not changing it would be best. The Subcommittee agreed that no updates are needed to the score recommendation or content for this diagnosis at this time.

Budd Chiari

A member indicated that they were unaware of any new literature that would warrant a score recommendation. A member voiced their opinion that the score recommendation should be median model for end-stage liver disease (MELD) at transplant (MMaT) -3, but that may not suffice if the candidate is very sick. A member noted that they believe that if there is no supporting evidence, the baseline recommendation score should be MMaT -3. A member agreed that MMaT -3 would be a good “floor” and another member agreed. A member pointed out that that may be the case for several diagnoses and there should be language that indicates that there is a baseline score is MMaT-3 with the potential to get more exception points at the discretion of the NLRB. A member agreed, along with another member, and supported the idea of having a paragraph at the beginning of the guidance document that outlines MMAT -3 as a baseline score recommendation for all diagnoses unless otherwise noted. The Subcommittee agreed that Budd Chiari should have an MMaT -3, and depending on the case, more priority may be warranted.

Gastrointestinal Bleeding

The Subcommittee agreed that no updates are needed to the score recommendation or the content for this diagnosis at this time.

Hepatic Encephalopathy

The Subcommittee agreed that no updates are needed to the score recommendation or content for this diagnosis at this time.

Hepatic Epithelioid Hemangioendothelioma (HEHE)

A member felt comfortable recommending this diagnosis to have an associated score of MMaT -3. A member noted that this section warrants review for possible content updates. A member indicated they were unsure what other detail they would offer that would be a result of the literature review. One member questioned if there was an updated reference the Subcommittee could include in the guidance document, thus they encouraged this diagnosis to undergo a literature review by members to see if there is anything to add.

Hepatic Hydrothorax

A member noted that they recently saw literature pertaining to this diagnosis that led them to believe that it may warrant a review for updated content. One member pointed out that it has not been reviewed in about five years, therefore it may be time to do so as well as provide a score recommendation based on the data. The Subcommittee agreed that this diagnosis should be reviewed.

Hereditary Hemorrhagic Telangiectasia

A member told the Subcommittee they viewed this as a low priority to review, however, they should review diagnoses every five years, and this falls into that cadence. They added that updating diagnoses every five years ensures that the data is recent and relevant. A member believed there is not much data out there to support a change but agreed that diagnoses should be periodically reviewed regularly. They added their uncertainty to find sufficient data or literature that would support adjusting a score to be above MMaT -3. A member countered that this diagnosis could result in heart failure and there are very few candidates who have this, thus it will not be severely impactful. A member reiterated that they are not confident that there is enough data to justify a score recommendation at this time. A member recommended starting at MMaT -3 with the potential to have a score increase if warranted. This received support from the Subcommittee, thus it will be reviewed and potentially updated.

Hepatic Adenomas

A member felt that this diagnosis needs a score recommendation, as it currently does not have one. A member agreed, noting that MMaT -3 would be an appropriate score recommendation for this diagnosis. The Subcommittee agreed.

Neuroendocrine Tumors

A member suggested MMaT -3 for this diagnosis and it received support.

Polycystic Liver Disease

The Subcommittee agreed that since this was recently reviewed, it does not need to be reviewed again at this time.

Portopulmonary Hypertension

The Subcommittee discussed the intent of having portopulmonary hypertension in the guidance since it is a standard criteria in Policy. Members noted that the guidance associated with this diagnosis is not substantial and does not offer any additional information. Members agreed that this section should be removed to avoid any confusion as the standard exception in policy should be the main pathway for candidates with this diagnosis.

Primary Sclerosing Cholangitis (PSC) or Secondary Sclerosing Cholangitis (SSC)

A member questioned why the guidance currently outlines that candidates must be cirrhotic, as they worry that will limit candidates with recurring cholangitis that are not necessarily cirrhotic. A member agreed and suggested the Subcommittee review these diagnoses to update content, as well as gave a score recommendation of MMaT -3.

Metabolic Disease

A member highlighted that very few candidates are diagnosed with metabolic disease. A member suggested adding something in for the Maple Syrup Urine Disease and giving those candidates a pathway for a MELD of 40. The Subcommittee agreed to review and potentially rewrite the guidance for this diagnosis.

Multi-Visceral Transplant Candidates

The Subcommittee agreed that this does not need to be updated, as it was developed recently.

Post-Transplant Complications: Small for Size Syndrome

A member noted that they felt this guidance language was a bit long and could benefit from being reviewed by the Subcommittee, as they feel new criteria may have been introduced in the literature. Another member indicated they thought this was a unique exception pathway because there are other pathways through MELD score of 40s or as a Status 1 candidate. One member agreed that a candidate's MELD score will reflect how ill they are with Small for Size Syndrome, and if not, they suggested that MMaT -3 should be adequate. A member indicated their concern that MMaT -3 would not give them enough priority, therefore candidates with this diagnosis should be reviewed on a case-by-case basis by the NLRB. A member advocated for having the score set to MMaT, and another member agreed. A member pointed out that there is no code for this diagnosis in the OPTN Computer System. One member agreed with setting the score recommendation to MMaT, noting that transplant programs can always ask for more if they need it. A member agreed that is a reasonable score for these candidates.

Post-Transplant Complications: Chronic Rejection

A member felt that this does not need to be updated, as they were unsure how you would give priority to chronic rejection candidates. A member agreed that this does not have to be updated.

Post-Transplant Complications: Diffuse Ischemic Cholangiopathy

The Subcommittee discussed potentially removing the donation after circulatory death (DCD) aspect of this guidance, as they felt it is now the same as donation after brain death (DBD).

Post-Transplant Complications: Late Vascular Complications

A member noted that the last time the Subcommittee reviewed this diagnosis, they considered extending the timeline from fourteen to thirty days. A member agreed that an extension to thirty days. Another member argued that it may be worth pushing it out to sixty days, as some recipients do not begin showing abscesses until day thirty. With that, the Subcommittee agreed that this should be reviewed and potentially change the timeline.

Post-Transplant Complications: Pruritis

The Subcommittee agreed that no changes are needed for this section of guidance.

Next steps:

The Subcommittee will present the refined project to the OPTN Liver & Intestinal Organ Transplantation Committee (the Committee) for approval. If agreed upon, the Committee will submit the project for consideration to the OPTN Policy Oversight and Executive Committees.

Upcoming Meetings

- April 9, 2024 @ 2 pm ET (teleconference)

Attendance

- **Subcommittee Members**
 - Allison Kwong
 - Chris Sonnenday
 - Kym Watt
 - Scott Biggins
 - Shimul Shah
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jack Lake
 - Katie Audette
 - Nick Wood
- **UNOS Staff**
 - Erin Schnellinger
 - Joel Newman
 - Katrina Gauntt
 - Kayla Balfour
 - Meghan McDermott
 - Niyati Upadhyay