

OPTN Executive Committee

Meeting Summary

March 19, 2024

Webex

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, Chair

Introduction

The OPTN Executive Committee met via Webex teleconference on 03/19/2024 to discuss the following agenda item:

1. Welcome and Announcements
2. Liver & Intestinal Organ Transplantation Committee Mini-Brief*
3. Expedited Placement Variance Proposal Update

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

1. Welcome and Announcements

Dianne LaPointe Rudow, Chair of the Executive Committee, welcomed the committee to the meeting and presented the agenda.

2. Liver & Intestinal Organ Transplantation Committee Mini-Brief*

Shimul Shah, Vice Chair of the Liver & Intestinal Organ Transplantation Committee, presented the mini-brief to Update Liver Diagnosis Code Nomenclature and Treatment Options for HCC Exceptions. Dr. Shah shared that the purpose of the proposal is to align OPTN forms with to new terminology related to metabolic dysfunction-associated with steatotic liver disease (MASLD) and new technology approved for the treatment of HCC.

Summary of Discussion:

A committee member asked if the new technology will honor previous extensions and exemptions that have been awarded to patients prior to the technology. The committee member wanted to ensure that these modifications to specific patients were reflected in the new technology. Dr. Shah explained that this will stay the same and the new technology will be used at a center's discretion.

Vote:

The committee unanimously approved the following:

RESOLVED, that the proposed modifications to response options within data collected by the OPTN, as set forth in the charts provided, are hereby approved, effective pending implementation and notice to OPTN members.

3. Expedited Placement Variance Proposal Update

James Alcorn, Senior Policy Strategist, reviewed special public comment feedback on the Expedited Placement Variance Proposal. Mr. Alcorn shared that the OPTN hosted a town hall for the community on March 13 to answer any questions and provide clarification on the proposal. He shared that during public comment, the overarching goal of the proposal received support, and the community had questions and concerns about the specifics of the proposal. He shared that the committee would be

asked to discuss guardrails, how to protect the sickest and most vulnerable candidates, how long to limit protocols, and who will decide which members can use which protocols.

Mr. Alcorn provided an example of a guardrail and asked the committee to consider which guardrails to include in the variance policy. The committee decided that pediatrics, race, and gender should be included as guardrails. The committee also discussed how members participating in the protocols should plan to allocate out of sequence. The committee decided that instead of having an overarching rule for members within the protocol, the Executive Committee and the Expeditious Task Force will review the process on a protocol-by-protocol basis. Mr. Alcorn noted that this approach will help to protect the sickest and most vulnerable candidates.

The committee discussed placing time limits on protocols. A committee member suggested 6 months as the time limit for each protocol, however, they did not want to limit the Executive Committee's ability to amend a protocol if the protocol is working well. The committee agreed that the time limit for protocols should be 6 months and that the time limit of protocols can be amended but cannot be extended.

The committee discussed member discretion throughout the protocol process and reviewed the feedback they provided during their prior meeting. Mr. Alcorn reviewed that members would volunteer to participate in the variance and the OPTN would choose which protocols members would participate in. The committee agreed that the OPTN should select who participates in each protocol, as this approach allows for more structure for analyzing the variance.

Next Steps:

Feedback from the committee will be incorporated into the document and the committee will vote on sending the final policy to the Board.

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Manish Gandhi
 - Melissa McQueen
 - Silas Norman
 - Wendy Garrison
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Frank Holloman
- **UNOS Staff**
 - Ann-Marie Leary
 - Anna Messmer
 - James Alcorn
 - Keighly Bradbrook
 - Krissy Laurie
 - Maureen McBride
 - Meghan McDermott
 - Morgan Jupe
 - Roger Brown
 - Susie Sprinson
 - Tony Ponsiglione
- **Other Attendees**
 - Shimul Shah