

OPTN Executive Committee

Meeting Summary

October 24, 2023

Webex

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

Introduction

The OPTN Executive Committee met via Webex teleconference on 10/24/2023 to discuss the following agenda item:

1. Transition Plan for HCC Auto Approval Correction Implementation*
2. Closed Session

1. Transition Plan for HCC Auto Approval Correction Implementation*

Contractor staff presented the proposed transition plan for Hepatocellular Carcinoma (HCC) auto approval correction implementation. Contractor staff shared that an issue was recently discovered where some candidates received automatic approval when they met some but not all of the imaging requirements. They shared that liver candidates with HCC are eligible for automatic approval of an exception request when meeting certain imaging and clinical criteria per OPTN Policy. Contractor staff shared that the issue could be amended with a system implementation. Contractor staff asked the Executive Committee to discuss and approve a transition plan to “grandfather- in” the 33 candidates with active exceptions who were automatically approved but did not meet all criteria.

Contractor staff shared some background information on HCC exceptions and noted that HCC is one of the nine conditions where OPTN Policy outlines standardized exception criteria.

Contractor staff presented the general criteria of HCC exception. These criteria include:

- Evaluation of number and size of Class 5 HCC tumors
- CT to rule out metastatic disease
- CT/MRI to rule out extrahepatic spread/macrovascular involvement
- Not eligible for resection
- Whether has had locoregional therapy
- Alpha-fetoprotein (AFP) level

Contractor staff shared HCC standard exception criteria and what auto-approved exceptions candidates would have to meet to apply for a standard. Contractor staff then shared OPTN Policy 9.5.I.vi Imaging Requirements for Class 5 Lesions and that the imaging requirements must meet the three criteria. The issue was occurring when the system was auto-approving HCC exceptions that only had two out of three class 5A required imaging criteria documented.

Contractor staff noted that if the transition plan was approved by the Executive Committee, candidates currently using an erroneous auto-approval would maintain that auto-approval upon implementation of a fix in the OPTN Computer System on October 25, 2023. The auto-approval would persist until further action was needed per OPTN policy due to expiration or extension.

Visitors from the Liver & Intestinal Organ Transplantation Committee, the Ethics Committee, and the Patient Affairs Committee (PAC), were asked to attend the meeting on behalf of their committees. Liver & Intestinal Organ Transplantation Committee leadership recommended that the 33 candidates retain their approved exception status and score upon the implementation on October 25. They noted that candidates would retain their approved exception status and score until it, otherwise, expired.

Contractor staff explained that if these candidates had not received automatic approval, they would have been routed through the NLRB review process and it is uncertain how they would have been adjudicated. These candidates also may have met the standardized imaging criteria at some point following initial approval based on clinical progression and the needed data may or may not exist. Contractor staff also explained that the standardized HCC MELD score is Median MELD at Transplant (MMaT), 3 days after 180 days from the initial approved exception. They noted that MMaT is based on the donor hospital which means the score changes with each match run. Lastly, contractor staff noted that the proposed transition plan is also generally consistent with transition plans for new policies. After explaining the transition plan, contractor staff also shared some of the alternative plans that were considered but not selected.

Summary of Discussion:

The committee discussed whether there were patients that could be disadvantaged due to this change. James Pomposelli, Chair of the Liver & Intestinal Organ Transplantation Committee, commented that it is important to consider the patients may currently be disadvantaged because of the issue. Dr. Pomposelli commented that the most straightforward transition plan would be to grandfather the 33 patients.

The committee discussed whether the exception would have an impact on patient's waiting time when considering whether or not to grandfather them in. The committee discussed that these patients could have also submitted approval through the Liver Review Board if they were not automatically approved. Visitors from other committees were asked to share feedback they received from their respective committee members. Representatives from both the Ethics and PAC committees shared their support that the 33 candidates that were automatically approved should be grandfathered in.

The committee discussed programing impacts associated with the issue and the importance of retrospective review. Contractor staff shared that a Root Cause Analysis (RCA) would be conducted. The committee was also interested to learn how the error occurred.

Vote:

The committee voted to approve the following resolution:

RESOLVED, that candidates at risk for HCC with Class 5A lesions with an active exception pursuant to OPTN Policy 9.5.I.vi: Imaging Requirements for Class 5 Lesions that was automatically approved prior to October 25, 2023 shall maintain their current exception score until it would otherwise expire pursuant to OPTN policy.

It was noted that this will include actively waiting liver candidates with an automatically approved HCC exception that did not meet all class 5A required imaging criteria. This number may change prior to implementation on 10/25/2023.

2. Closed Session

The committee met in a closed session.

The meeting was adjourned.

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Manish Gandhi
 - Melissa McQueen
 - Richard Formica
 - Valinda Jones
 - Wendy Garrison
- **HRSA Representatives**
 - Christopher McLaughlin
 - Daniel Thompson
- **UNOS Staff**
 - Anna Messmer
 - Cole Fox
 - Julie Nolan
 - Kayla Balfour
 - Lauren Mauk
 - Liz Robbins Callahan
 - Maureen McBride
 - Michael Ghaffari
 - Morgan Jupe
 - Rebecca Murdock
 - Roger Brown
 - Susan Tlusty
 - Tony Ponsiglione
- **Other Attendees**
 - Garrett Erdle
 - James Pomposelli
 - Molly McCarthy
 - Sanjay Kulkarni