OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board Subcommittee
Meeting Summary
February 13, 2020
Conference Call

James Trotter, MD, Committee Chair
James Pomposelli, MD, PhD, Committee Vice Chair
Julie Heimbach, MD, Subcommittee Chair

Introduction

The National Liver Review Board (NLRB) Subcommittee (the Subcommittee) met via teleconference on 2/13/2020 to discuss the following agenda items:

1. HCC Auto-Approval Turn Down Reasons
2. Portopulmonary Hypertension Policy
3. HCC Explant Policy

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

1. HCC Auto-Approval Turn Down Reasons

As a follow-up to a data request, the Subcommittee reviewed turn-down reasons for HCC exception request forms not meeting automatic approval criteria.

Summary of Data

The Subcommittee reviewed:

- Exception request forms by HCC, by application type and policy criteria and auto-approval status
- Exception request forms for HCC not meeting policy criteria and reviewed by NLRB, by application type and outcome
- Initial exception request forms for HCC with 0 tumors, determined as a form with 1 tumor recorded as size 0 cm, by outcome

The report concluded:

- Most common initial exception request form for HCC automatic approval turn down reasons and outcomes
    - When only one reason was cited, it was most commonly :
        - "Most recent tumor number and/or size falls below Stage T2 HCC"
        - "T2 not meeting imaging criteria"
    - When two reasons were cited,
        - "Most recent tumor number and/or size falls below Stage T2 HCC" and
        - "Original/Presenting Tumor number and/or size exceeds downstaging eligibility requirements"
    - There were 12 forms with three total turn-down reasons
    - There was 1 form with four turn-down reasons

- Most common extension exception request form for HCC automatic approval turn down reasons and outcome
    - When only one reason was cited, it was most commonly :
        - "Extension is not automatically approved if a previous application did not meet the criteria outlined in policy."
        - "T2 not meeting imaging criteria"
    - When two reasons were cited,
        - " Extension is not automatically approved if a previous application did not meet the criteria outlined in policy." and "Two (2) tumors are indicated and one or more of the tumors is greater than 3 cm"
- Reviewing the initial form turn-down reasons for extension requests turned down due to a previous application not meeting policy criteria provides the original automatic approval turn down reason(s) in these cases.
    - When one reason was originally cited, it was most commonly: "Most recent tumor number and/or size falls below Stage T2 HCC"
    - "T2 not meeting imaging criteria"
- When two reasons were cited,
    - ""Original/Presenting Tumor number and/or size exceeded T2 and no loco-regional treatment" and "Most recent tumor number and/or size falls below Stage T2 HCC"

Summary of Discussion

The Subcommittee discussed the accuracy of the data on request forms for HCC with 0 tumors and whether the data reflects HCC patients who have been previously treated for tumors or if information is being entered incorrectly. A suggestion was made to review these exception applications to compare those who were approved and denied by the NLRB. Some of the issues may also be corrected after implementation of NLRB enhancements.

2. Portopulmonary Hypertension Policy

The Subcommittee reviewed current OPTN policy standard criteria for MELD Exception for Portopulmonary Hypertension.

> *OPTN Policy 9.5.G*
>
> *A candidate will receive a MELD or PELD score exception for portopulmonary hypertension if the transplant hospital submits evidence of all of the following:*
>
> 1. *Initial mean pulmonary arterial pressure (MPAP) level*
> 2. *Initial pulmonary vascular resistance (PVR) level*
> 3. *Initial transpulmonary gradient to correct for volume overload*
> 4. *Documentation of treatment*
> 5. *Post-treatment MPAP less than 35 mmHg within 90 days prior to submission of the initial exception*
> 6. *Post treatment PVR less than 400 dynes*sec/cm^{-5}, or less than 5.1 Wood units (WU), on the same test date as post-treatment MPAP less than 35 mmHg*

A Subcommittee member proposed the following revisions to the policy:

- Maintain current criteria: mPAP < 35 mmHg and PVR < 400 dynes*sec/cm-5, or less than 5.1 Wood units (WU)
- Also allow exception if treatment results in mPAP < 45 mmHg with normalization of PVR (< 240 dynes.s.cm-5 or 3 wood units)

- Minimum MELD-NA of 12 required to obtain a MELD exception for POPH
- Need for sequential right heart catheterization every 3 months to maintain exception has been questioned
- Suggestion to add/have available a pulmonary hypertension expert consultant, with POPH experience, to the national review board to review cases and/or appeals

Summary of Discussion and Next Steps

The Subcommittee members discussed their own experiences with POPH and the policy. This issue will go to the full Committee for discussion.

3. HCC Explant Policy

The Subcommittee reviewed a section of *OPTN Policy 9.6.I.i Initial Assessment and Requirements for HCC Exception Requests*:

> *For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the Post-Transplant Explant Pathology Form to the OPTN Contractor within 60 days of transplant.* ***If the pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in a one-year period are not supported by the required pathologic confirmation or submission of clinical information.***

The Subcommittee was informed the policy is difficult to operationalize as written as UNOS staff cannot make clinical decisions regarding if the additional documentation shows evidence of HCC. Furthermore UNOS site surveyors do not review Explant Pathology forms.

Next Steps

The Subcommittee proposed the following solution:

- Change policy so that a transplant hospital is reviewed by the Liver Committee if > 10% of Explant Pathology forms in a year show no evidence of HCC and **no treatment of HCC**
- Additional documentation is only submitted once the 10% threshold is met and program is being reviewed by Liver Committee

These options will be discussed further during a full committee call.

Upcoming Meetings

- March 12, 2020

Attendance

- **Subcommittee Members**
  - Scott Biggins
  - Kimberly Brown
  - Jennifer Kerney
  - James Trotter
  - Sarah Jane Schwarzenberg
  - Patricia Sheiner
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Matt Cafarella
  - Samantha Noreen
  - Karen Williams
  - Kimberli Combs
  - Jennifer Musick
  - Leah Slife
- **Other Attendees**
  - Mike Krowka
  - Evelyn Hsu