OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Summary
May 26, 2016
Conference Call

Ryutaro Hirose, MD, Chair
Julie Heimbach, MD, Vice Chair

Discussions of the full committee on May 26, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. National Liver Review Board

The Chair of the MELD Exceptions and Enhancements Subcommittee provided an update of the group's efforts in developing guidance for assessing adult MELD exception requests. The National Liver Review Board (NLRB) will use these recommendations to evaluate requests for adult candidates with the following diagnoses, not all of which are appropriate for MELD exception:

- Ascites
- Budd Chiari
- GI Bleeding
- Hepatic Encephalopathy
- Hepatic Epithelioid Hemangioendothelioma
- Hepatic Hydrothorax
- Hereditary Hemorrhagic Telangiectasia
- Multiple Hepatic Adenomas
- Pruritus

Based on feedback received from the Committee, the guidance will also include recommendations for candidates with post-transplant complications, including small for size syndrome, chronic rejection, diffuse ischemic cholangiopathy, and late vascular complications. The Committee anticipates voting to send the proposed adult guidance for public comment during its June 16 teleconference.

The Subcommittee Chair has also convened a joint working group with the OPTN/UNOS Pediatric Transplantation Committee to develop similar guidance for assessing pediatric MELD/PELD exception requests. The guidance will include recommendations for evaluating Status 1B requests, as well as four common types of PELD exceptions including:

- Chronic Liver Disease
- Post-Transplant Complications
- Congenital Portosystemic Shunts
- Neoplasms

A date has not yet been set to vote to send the proposed pediatric guidance for public comment.

2. Changes to HCC Criteria for Standardized MELD Exception

The current criteria for standardized HCC exception is problematic, in that it includes patients that may do well without liver transplant or that have a poor prognosis after transplant, and potentially excludes patients that may benefit from liver transplant. Additionally, language describing the eligibility criteria for candidates suitable for HCC downstaging through local-regional treatment is absent from current OPTN policy. However, nearly all Regional Review Boards (RRBs) currently approve patients who present outside of T2 criteria and have undergone downstaging to within T2. Evidence suggests that successful downstaging of HCC in select patients is associated with positive post-transplantation outcome.

The Chair of the MELD Exceptions and Enhancements Subcommittee provided an update of the group's progress in developing a proposal to revise the HCC eligibility criteria for standardized MELD exception. The Subcommittee is considering the following policy changes.

Candidates with Single Small Lesions

- Candidates who initially present with a single lesion between 2 and 3 cm and alpha-fetoprotein (AFP) less than 20 ng/mL are required to undergo local-regional therapy prior to applying for a standardized MELD exception. Transplant programs can ask the HCC review board to review cases in which they feel that local-regional therapy is contraindicated.

Candidates with Lesions Eligible for Downstaging Protocols

- Candidates that meet one of the following criteria are eligible for inclusion in a downstaging protocol:
    - One lesion greater than 5 cm and less than or equal to 8 cm
    - Two or three lesions each less than 5 cm and total diameter of all lesions less than or equal to 8 cm
    - Four or five lesions each less than 3 cm and total diameter of all lesions less than or equal to 8 cm
- Candidates who are eligible and then complete local-regional therapy must subsequently meet the requirements for T2 lesions.

Candidates with Alpha-fetoprotein (AFP) levels greater than 1,000 ng/mL

- Candidates with lesions meeting T2 criteria but with an AFP greater than 1,000 ng/mL are not eligible for a standardized MELD exception.

The Committee discussed whether candidates with single small lesions, as described above, would be required to wait at the calculated MELD score for 6 months upon recurrence or if the candidate develops a new lesion. Members expressed support for not requiring an additional 6 month delay in the assignment of the exception score. The Committee also discussed whether candidates with AFP greater than 1,000 ng/mL should receive a standardized exception if their levels drop to 500 ng/mL or less. The Committee also discussed whether candidates should have to maintain an AFP of 500 ng/mL or less upon extension.

Other Significant Items

3. The Committee reviewed the analysis plans for two outstanding modeling requests, including:

- sharing adult deceased donor livers district-wide for candidates with a MELD or PELD of at least 25, 29, and 35 before allocating within the DSA
- assigning adult exception candidates fixed MELD scores that are 1, 2, 3, and 5 points below the median allocation MELD of all recipients in the DSA where the candidate is listed

Upcoming Meetings

- June 16, 2016
- June 27, 2016