

OPTN/UNOS Liver & Intestinal Organ Transplantation Committee
Meeting Minutes
April 20, 2017
Conference Call

Ryutaro Hirose, MD, Chair
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Introduction

The Liver & Intestinal Organ Transplantation Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 04/20/2017 to discuss the following agenda items:

1. National Liver Review Board (NLRB) Post-public Comment Discussion and Voting

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

1. NLRB Post-public Comment Discussion and Voting

The Committee reviewed public comment on the NLRB Guidance Documents and NLRB Policy Proposal and discussed post-public comment changes and voted to send the NLRB proposal and guidance documents to the OPTN/UNOS Board of Directors in June 2017

Summary of discussion:

NLRB Guidance Documents

The Committee was presented with the public comment on the NLRB Guidance documents and the recommendations from the Subcommittee regarding the Hepatocellular Carcinoma (HCC) Guidance Document. The Subcommittee previously recommended that the Committee modify the guidance regarding ruptured HCC and primary portal vein branch invasion from what was submitted for public comment. The recommendation from the subcommittee was a clarification regarding patients with ruptured HCC and/or primary portal vein branch invasion. The subcommittee recommendation stated that some patients who remain stable for a prolonged interval after treatment for primary portal vein branch invasion, or ruptured HCC, may be suitable for consideration of an exception. A committee member stated that "prolonged interval" may not be specific enough and that a timeframe may be necessary. The Committee discussed 12 months versus 24 months as the period of prolonged interval. The Committee agreed that specifying a minimum of 12 months needed to be added to the HCC guidance.

The Committee was presented with new guidance language regarding HCC candidates that recur after resection, and the consideration that some of these candidates would not require the standard 6 month delay. A committee member asked about the scenario where a patient recurs within 3 months of resection, if that isn't a sign of aggressive tumor biology and would necessitate the need for the 6 month delay. A committee member reiterated that this guidance was not for standardized exceptions, and that any scenario would be adjudicated by the HCC specialty board of the NLRB. Several committee members stated that they were unsure whether recurrence of a small lesion (1 centimeter) was rationale to not have the same 6 month delay as other HCC candidates. A committee member stated that if the Committee included language that the T1 lesions were biopsy proven, then they could be considered for not meeting the 6 month delay. Several committee members agreed that it's beneficial to have some level of encouragement for candidates to pursue resection. The Committee agreed that the guidance would include that recurrent T1 tumors would need to be biopsy proven in order to not have a 6 month delay. The Committee voted 14 approve, 0 oppose, 0 abstentions to send the modified guidance to the Board of Directors for consideration in June 2017.

The Committee was presented with the public comment on the *Proposal to Establish a National Liver Review Board*. This included feedback from the regional meetings, professional societies, and general public. The majority of feedback from the regional meetings was focused on the use of the Donor Service Area (DSA) or region, as the geographical unit for the calculation of a median MELD at Transplant (MMaT) calculation. The MMaT calculation is used as a fixed score for exception candidates. 7 regions supported the MMaT score by the DSA and supported the scoring be based on the Region. The other significant feedback during public comment focused on the idea that the MMaT score should be calculated by blood type. Prior to this meeting the subcommittee discussed this feedback and recommended the score be based on MMaT by the DSA and for the MMaT to include all blood types.

A Committee member stated that the usage of “marginal” organs in low-MELD candidates would drive down the MMaT in the DSA which could be viewed as disadvantaging other centers in the DSA by lowering the MMaT score for exception candidates. A committee member stated that by excluding nationally allocated livers from the MMaT calculation, this may remove the concerns about the usage of “marginal” organs in low-MELD candidates lowering the MMaT score. A committee member suggested that the MMaT score should be calculated by local, regional, and national allocation. Therefore, the MMaT score for a candidate would be based on the candidates within each geographical calculation. A committee member supported this idea, while others suggested that this may be confusing for the candidate and potentially not feasible to program. The majority of the Committee ultimately felt that by excluding national offers from the MMaT calculation, the concerns for the use of “marginal” organs lowering the MMaT in the DSA were addressed.

The Committee discussed whether to calculate the MMaT by blood type, or to include all blood types in the calculation. A committee member stated that when they looked at the data regarding MMaT by blood type in the nation, there was not considerable variation to necessitate the policy that went out for public comment which included all blood types. The Committee voted to approve the proposal as written in public comment, with the amendment that national offers would be excluded in the DSA MMaT calculation, 9 approve, 4 oppose, 0 abstentions. A committee member reiterated the fact that there will be a robust monitoring plan in place post-implementation to ensure that the proposal is achieving its goals and monitoring any potential deleterious effects.

Upcoming Meetings

- May 8, 2017 (Chicago)
- May 18, 2017 (teleconference)
- June, 15, 2017 (teleconference)