OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting Minutes December 1, 2017 Conference Call

Julie Heimbach, M.D., Chair James Trotter, M.D., Vice Chair

Introduction

The Liver and Intestinal Organ Transplantation Committee (Committee) met via teleconference on 12/1/2017 to discuss the following agenda item:

1. Discussion of Change to Lung Allocation

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

1. Discussion of Change to Lung Allocation

Summary of discussion:

The Committee met to review the recent changes to lung allocation brought on by a legal challenge to previous lung allocation policy. UNOS leadership presented the sequence of events over the last week. A letter was sent to the Secretary of Health and Human Services (HHS) on November 16th that argued the use of DSA as the first unit of allocation contravenes NOTA, Final Rule, and medical judgement, and requested the removal of classifications 1-6 in current lung allocation policy. A subsequent argument in court filings resulted in HHS directing the OPTN to review use of DSA in lung allocation policy. The OPTN/UNOS Executive Committee met twice to review the directive and discuss options. The Executive Committee concluded that lung allocation policy could be revised by replacing the DSA as the first unit of lung allocation with a 250 mile circle around the donor hospital. The change to policy was implemented on Friday, November 24th.

With the upcoming OPTN/UNOS Board of Directors meeting in December 2017, the Committee was informed that several amendments had been submitted for consideration by the Board of Directors. The Committee discussed the implications of the change to lung allocation on the current liver proposal under consideration by the Board of Directors. It was stated that there are notable differences between the use of the DSA in liver and lung policies. A committee member replied that the reliance on DSA in lung policy was unique, and that liver policy has less reliance on the DSA, and that extensive time has been spent on developing the current liver proposal. A committee member pointed out that the changes to lung allocation were implemented by UNOS very quickly, and that it would be important for any liver changes to also be implemented quickly so that the community could study the effects soon. UNOS staff stated the changes to liver policy is much more complex and could not be implemented as quickly as the changes to liver policy.

Several committee members discussed the defensibility of the use of DSAs in the new liver policy. It was stated that liver allocation in the proposed policy does not prioritize the DSA except for DCD donors and donors greater than 70 years old. Additionally, it was stated by a committee member that there is also proximity points provided to candidates in the DSA or 150 mile circle around the donor hospital. Allocation in the proposed policy is to the Region and 150 mile circle for all candidates with a MELD/PELD at least 32 before allocating to candidates in the DSA to a MELD/PELD of 15, for donors greater than 18 years old and less than 70. A committee member asked whether it was the arbitrary nature of the DSA boundaries that is the

issue, or whether it was a geographic disparity in access to transplant. It was stated that the boundaries used for organ allocation need a clinical or operational rationale that can be defended. The committee confirmed that there are clinical restraints on the distance that a liver could and should be allocated, so constraints are necessary but need to be rationally defined based on clinical and operation considerations.

The Committee reviewed the amendments that had been submitted to the Board of Directors to the current liver proposal. Several committee members stated their support for the process that led to the current proposal and their resistance to the Board of Directors approving new amendments, and that it may undermine the work of the Committee.

Next Steps:

The OPTN/UNOS Board of Directors is meeting on December 4th, 2017 to consider the committee's current proposal.

Upcoming Meetings

• December 21, 2017