

OPTN/UNOS Thoracic Organ Transplantation Committee Meeting
July 16, 2012
Teleconference and Live Meeting
6:00 pm to 7:00 pm (Eastern)

Committee Members: Luis Angel, Mark Barr, Nancy Blumenthal, Linda Bogar, Kevin Chan, Leway Chen, Joe Cleveland, Rocky Daly, Kevin Dushay, Brad Dyke, Shelley Hall, Mariska Kemna, Laurie Loza, Bill Mahle, Dan Meyer, Joe Rogers, Gary Visner, Steven Webber, Tim Whelan, Gordon Yung

SRTR Staff Members: Monica Colvin-Adams, Brooke Heubner, Tabitha Leighton, Melissa Skeans, Maryam Valapour

HRSA Representatives: Ba Lin, Monica Lin

UNOS Staff Members: James Alcorn, Leah Edwards, Elizabeth Miller, Jory Parker, Liz Robbins

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations that occurred by telephone and Internet on July 16, 2012.

Review of Heart Regional Review Board Denial to Grant Status 1A Exception Extension Request

The Committee reviewed a case from May 2012, in which the transplant center requested an extension from the Regional Review Board (RRB) to continue to list a candidate as Status 1A by exception. The RRB denied the request because the candidate did not have sustained ventricular tachycardia, or sustained need for shocks. The Committee reviewed the transplant center's request and supporting evidence, but ultimately agreed with the RRB's decision to deny the extension request based on the information available to the RRB. The Committee voted 18 – 0 (with one abstention) in favor of the RRB's decision (18 supported; 0 opposed; 1 abstained).

The Committee also voted to recommend to the requesting transplant center to resubmit the case to the RRB if they would like to pursue the option of reinstating any Status 1A time the candidate may have lost, if the candidate could have otherwise been listed as Status 1A under a different criterion during the time it took for the Committee to review and decide the case. (18 supported; 0 opposed; 1 abstained).

In the future, the Thoracic Committee hopes to make the process for reviewing RRB cases referred to the Committee much quicker.

Review of Waiting Time Modification Request

The Committee then reviewed a case submitted by a transplant center, requesting a waiting time modification for a candidate due to a clerical error on the part of the transplant center. The Committee agreed that for clerical errors, the Committee generally assumes that the requesting center made an honest mistake and therefore will approve requests to modify the candidate's waiting time. The Committee voted in favor of reinstating the candidate's time (19 supported; 0 opposed; 0 abstained).

Discussion of Public Policy Proposals to be Distributed in September, 2012 for the Fall Public Comment Cycle

Heart-Lung Bylaw Removal

The Committee voted in favor of distributing the Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation (20 supported; 0 opposed; 0 abstained).

30 Day Status 1A Time for Outpatient TAH Candidates

The Committee next discussed whether to distribute the Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time for public comment. The policy was originally approved as a temporary policy in November 2010, extended in November 2011, and is due to expire December 1, 2012, unless the Committee votes to extend the policy. UNOS staff recommended sending the policy out for public comment while the Committee debates whether to extend the policy.

Data collected on TAH patients since November 2010 show only 14 outpatient TAH patients were listed as Status 1A for 30 days under the outpatient TAH provision between November, 2010 and April, 2012. The Committee noted that the number of candidates benefitting from this provision is significantly less than the original estimate given to the Committee by TAH manufacturers, based on the number of candidates they anticipated would participate in the clinical trial, when the policy was originally approved in 2010. The Committee was hesitant to make the policy “permanent” due to the lack of data to support extending the policy. Additionally, the Committee agreed that outpatient TAH candidates may not be as medically urgent as certain other patients, including some outpatient VAD patients, and the policy therefore unnecessarily may advantage outpatient TAH patients.

The Committee understood that if the proposal is not distributed for public comment, the current policy will expire in December. The Board is unlikely to approve any last-minute extension requests at the November 2012 Board meeting without seeing a good faith effort from the Committee to distribute the proposal for public comment.

Ultimately, the Committee did not vote to distribute the policy for public comment, and tabled the proposal. The provision in Policy 3.7.3 granting outpatient TAH candidates 30 days of Status 1A time after discharge will therefore expire on December 1, 2012. The heart subcommittee will focus this fall on whether any further allocation policy changes should be developed for the TAH population, without any further action from the Board.

Pediatric Heart Allocation Modification

Next, the Committee reviewed the status of the Pediatric Heart Allocation Modification policy. The Committee, along with the Pediatric Transplantation Committee, originally anticipated the policy would be ready for distribution for public comment for the Fall, 2012 cycle. The proposed policy language is still not finalized, however, and therefore will likely not be distributed until the Spring, 2013 public comment cycle. The Committee agreed to try to convene to review and vote to distribute the policy for public comment if the policy language and proposal are completed in about the next two weeks.

Update on Activities of the RRB Streamlining Workgroup

The Committee received an update on the RRB streamlining project. The RRB workgroup is currently focused on administrative topics, such as setting standards for quorum and majority, voting, assigning

alternate voting review board members, tiebreakers, and how to treat extension requests that coincide with pending exception appeals. Substantive changes to policies and guidelines will not be implemented at this time. The subcommittees will be able to review the new RRB guidelines during their teleconferences in August 2012. The Executive Committee is scheduled to review and decide whether to adopt the RRB Workgroup's recommendations in late August, 2012.