

OPTN/UNOS Thoracic Organ Transplantation Committee
Report to the Board of Directors
November 8-9, 2010
St. Louis, Missouri
Summary

I. Action Item For Board Consideration

- *Modification to Policy 3.7.3 (Adult Candidate Status) for Outpatient Candidates with Total Artificial Hearts*

The Board is asked to approve an interim change to total artificial heart policy while the Committee considers the long-term impact of the new technology and develops a recommendation for a permanent policy change. (Item 1, page 3)

II. Other Significant Items

- *Committee-Sponsored Public Comment Proposals*

On October 1, 2010, the Committee distributed the following proposals for public comment: 1) Addition of Human Leukocyte Antigen (HLA) to Policy 3.7.12.1 (Essential Information); and 2) Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM. (Item 2, page 5)

- *Updating the Lung Allocation Score (LAS) System – SRTR’s Efforts*

The Committee continues its effort to update the waiting list and post-transplant models using data collected since 2005, and will submit a public comment proposal to revise the LAS in 2011. (Item 3, page 10)

- *Effort to Revise Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates)*

The Committee continues its efforts to revise Policy 3.7.7 to include geography, medical urgency of Status 1B, lung transplant candidates, and pediatric candidates. (Item 4, page 13)

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Mark Barr, MD, Chair
Steven Webber, MD, Vice-Chair

The Thoracic Organ Transplantation Committee (Committee) met by teleconference on June 7, 2010, and in person in Chicago, Illinois on September 2, 2010. The following is a summary of the Committee's deliberations:

1. Modification to Policy 3.7.3 (Adult Candidate Status) for Outpatient Candidates with Total Artificial Hearts (TAH)

The policy on candidates with TAHs was written at a time when such candidates could not be discharged from the hospital. The Committee first discussed as a group the current adult heart medical urgency policy on TAHs in light of the recent discharge of a heart transplant patient with a TAH. This patient left to await a heart transplant at home due to the recent development of a portable home driver.

The Committee discussed what interim guidance to provide to the thoracic community on classifying the medical urgency status of candidates with TAHs who are discharged from the hospital. The Committee approved (22-supported; 0-opposed; and, 0-abstained) and delivered a letter reminding the thoracic community that current policy requires TAH candidates to be in the hospital to retain their 1A status, and that until a policy change can be considered, discharged patients must be listed as Status 1B.

The text of the letter follows:

An adult heart transplant candidate with a total artificial heart (TAH) implant qualifies for Status 1A if this individual is hospitalized while waiting for a deceased donor heart. A transplant center may list a candidate with a TAH implant at Status 1A for 14 days, which can be extended in 14-day periods if the treating physician certifies to UNOS that the candidate still has a TAH and is hospitalized.

If a transplant center discharges a candidate with a TAH implant from the hospital to await a deceased donor heart at home, then the candidate qualifies for neither Status 1A nor 1A exception. Policy 3.7.3 and current UNOS processes require that a candidate with a TAH that is discharged home should be downgraded to Status 1B immediately. A candidate with a TAH implant and experiencing complications or infections due to the device qualifies for Status 1A, regardless of hospitalization status (see Policy 3.7.3 – Status 1A, criterion b). If you have questions about the UNOS process on changing a candidate's heart status, please contact Mr. Aaron McKoy at mckoyar@unos.org or 804-782-6575 (extension # 6575).

Policy is not intended to penalize a candidate with TAH and discharged home on the portable driver.

Due to change in technology in managing transplant candidates with total artificial hearts, the Thoracic Organ Transplantation Committee is working on revising Policy 3.7.3

(Adult Candidate Status) to more specifically address the appropriate medical urgency status of a candidate with a TAH implant and awaiting a donor heart at home.

To read Policy 3.7.3 in its entirety, please visit the web site linked below and click on the document with the title, “Organ Distribution: Allocation of Thoracic Organs.”

<http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>

If you have questions for the Thoracic Organ Transplantation Committee, please contact Ms. Vipra Ghimire at ghimirev@unos.org or 804-782-4071.”

Upon distribution of the aforementioned letter, the Committee received feedback that outpatient candidates with TAHs should be classified Status 1A. The clinical trial that involves the portable driver has to date enabled the discharge of two candidates in the United States. Anecdotal data provided by physicians and surgeons in the thoracic community suggest that this patient group may warrant 1A status. Of significance is the fact that if these candidates did not participate in the clinical trial, they would have remained inpatients, and would have continued to receive the Status 1A classification.

The Committee developed a two-step plan for considering changes to policy regarding TAH and ventricular assist device (VAD). First, the Committee requests the Board to approve an interim policy change at its meeting on November 8-9, 2010. The Committee proposes that outpatient candidates with TAHs be classified Status 1A for 30 days. Once this time period expires, and the outpatient candidate does not meet any criterion for Status 1A, the candidate must be listed as Status 1B. The Committee recommends that the proposal take effect on November 10, 2010, be distributed for public comment in March, 2011, and have an expiration date of December 1, 2011. This public comment proposal, which provides a justification for the proposed policy is **Exhibit A** (page 6 of this report). The document describing the resources required to implement the policy is **Exhibit B** (page 15 of this report).

On October 29, 2010, the Committee discussed and voted on the proposed policy language on outpatient candidates with TAHs. The Committee voted in favor of pursuing modifications to Policy 3.7.3 (18-Supported; 0-Opposed; and, 1-Abstained) and recommends the following policy language and resolution for the Board’s consideration.

****RESOLVED, that Policy 3.7.3 (Adult Candidate Status) shall be modified as set forth below, effective November 10, 2010, concurrent with public comment:**

3.7.3 Adult Candidate Status. Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows:

Status	Definition
1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A(b) candidates) and has at least one of the following devices or therapies in place:

- (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
 - (i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
 - (ii) total artificial heart;
 - (iii) intra-aortic balloon pump; or
 - (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.

[...]

- 1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:
 - (aa) left and/or right ventricular assist device implanted; or
 - (bb) continuous infusion of intravenous inotropes.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

[There are no further changes to Policy 3.7.3]

After public comment and before the expiration of the interim policy, the Committee will ask the Board to consider a broader set of changes to the TAH and VAD¹ policies. Historically, candidates with TAHs did not fare as well as candidates with VADs. Current experience of physicians and surgeons on the Committee suggests that candidates with TAHs appear to fare better than candidates who receive both a left and a right VAD, i.e., Bi-VAD. The Committee will review data to determine whether continuous Status 1A eligibility is still justified for inpatient TAH candidates. If data show similar outcomes for TAH and VAD candidates, future policy on candidates with TAHs and VADs may be similar. The Committee will review data regarding outcomes for TAH and VAD patients and propose a comprehensive review of TAH and VAD policies for future public comment and Board consideration.

¹ Currently, candidates with VADs – experimental or non-experimental – are classified as Status 1A for 30 days, unless they experience device-related complications; otherwise, these candidates are classified as Status 1B.