At-a-Glance

- **Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time**

- **Affected Policy:** 3.7.3 (Adult Candidate Status)

- **Thoracic Organ Transplantation Committee**

  On November 9, 2010, the OPTN/UNOS Board of Directors (Board) approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. These candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates are not eligible to be listed as Status 1A by other existing criteria, then they must be downgraded and may be listed as Status 1B. **This interim policy is in effect and is comparable to the Status 1A policy for candidates with ventricular assist devices (VAD).**

  Recent availability of a portable driver has allowed some candidates with TAHs to await heart transplantation as outpatients. Prior to the availability of this new portable driver, all candidates with TAHs remained inpatients. Policy allows all inpatient TAH candidates to be classified as Status 1A for 14 day periods; however, policy previously prevented outpatient candidates implanted with TAHs to be listed as Status 1A unless they qualified for Status 1A by criterion (b).[A] There are no data to suggest that the medical urgency of an inpatient candidate with a TAH implant is different from an outpatient candidate with a TAH implant. Therefore, the Thoracic Committee proposes to temporarily provide this outpatient candidate some time at Status 1A while it gathers evidence for developing a long-term policy on outpatient candidates implanted with TAHs. This interim policy will expire on December 1, 2011.

- **Affected Groups**
  Adult, Outpatient Heart Transplant Candidates with TAHs
  General Public
  Other Adult Heart Transplant Candidates
  Transplant Administrators
  Transplant Coordinators
  Transplant Physicians and Surgeons
  Transplant Program Directors

- **Number of Potential Candidates Affected**
  The proposed policy applies to adult outpatient candidates with TAHs.

- **Compliance with the OPTN Final Rule**
  - "§ 121.8 Allocation of organs. […] (a) Policy development. […] (5) Shall be designed to …promote patient access to transplantation…(6) Shall be reviewed periodically and revised as appropriate;" […]

[A] Status 1A, criterion (b): "Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias […]"

Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with TAHs Thirty Days of Status 1A Time

Affected Policy: 3.7.3 (Adult Candidate Status)

Thoracic Organ Transplantation Committee

Summary of the Proposal:

On November 9, 2010, the Board approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. These candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates are not eligible to be listed as Status 1A by other existing criteria, then they must be downgraded and may be listed as Status 1B. **This interim policy is in effect and is comparable to the Status 1A policy for candidates with ventricular assist devices (VAD).**

Recent availability of a portable driver has allowed some candidates with TAHs to await heart transplantation as outpatients. Prior to the availability of this portable driver, all candidates with TAHs remained inpatients. Policy allows all inpatient TAH candidates to be classified as Status 1A for 14 day periods; however, policy previously prevented outpatient candidates implanted with TAHs be listed as Status 1A unless they qualified for Status 1A by criterion (b). There are no data to suggest that the medical urgency of an inpatient candidate with a TAH implant is different from an outpatient candidate with a TAH implant. Therefore, the Thoracic Committee proposes to temporarily provide this outpatient candidate some time at Status 1A while it gathers evidence for developing a long-term policy on outpatient candidates implanted with TAHs. This interim policy will expire on December 1, 2011.

Background and Significance of the Proposal:

A TAH is a device implanted in an individual whose left and right heart ventricle fails to pump blood due to end-stage heart failure.[B] Two companies presently manufacture TAHs and these mechanical circulatory support devices have been approved by the Food and Drug Administration (FDA) of the United States. SynCardia Systems, Inc. (SynCardia) manufactures the "SynCardia temporary Total Artificial Heart"[C] and Abiomed manufactures the "AbioCor Implantable Replacement Heart."[D] SynCardia's TAH uses a power source external to the body to pump blood through the artificial heart. Abiomed's TAH makes use of a power source implanted in the body, but maintained by a "magnetic charger" external to the body.[B]

Until May, 2010, no candidate with a TAH awaited a heart transplant as an outpatient. In May, 2010 and since, at least two hospitals have discharged candidates with TAHs; and, more such discharges are expected. Several hospitals in the United States are participating in an investigational device exemption (IDE) study, approved by the FDA, to assess the effectiveness of the SynCardia's Freedom™ Driver system. This IDE is in a clinical trial that has the following purpose:

> "The purposes of this study are to confirm that the Freedom Driver System is suitable pneumatic driver for clinically stable TAH-t subjects, and that patients and lay caregivers can be trained to

[B] http://www.nhlbi.nih.gov/health/dci/Diseases/tah/tah_what.html
[C] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm080816.htm
[D] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077536.htm

> manage the Freedom Driver System safely outside the hospital."[E] (The National Institutes of Health's (NIH) Freedom™ Driver's clinical trial identifier number is NCT00733447.)

As posted to the NIH's "clinicaltrials.gov" web page (see footnote "E"), SynCardia's clinical trial may result in as many as 60 patients discharged with the portable driver.

In order to qualify for Status 1A for 14-day time periods, Policy 3.7.3 required candidates with TAHs to be admitted to the listing hospital. Previously, policy and its implementation in UNet℠ only classified an outpatient candidate with a TAH as Status 1B. Because there have been no outpatient TAH candidates until 2010, there are no data to indicate whether their medical urgency for transplant should be lower upon discharge from the hospital. The Thoracic Committee's September, 2010 communication to the heart transplant community, which clarified that Policy 3.7.3 requires candidates with TAHs to be inpatients to qualify for the 1A status, generated responses that this lower medical urgency categorization upon discharge from the hospital medically disadvantages this emerging group of patients. As a compromise, the Thoracic committee proposed the following temporary amendment to Policy 3.7.3 to allow these candidates to be eligible for listing as Status 1A for 30 days after discharge while it continues to develop a long-term policy that best classifies their medical urgency:

> 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.

On November 9, 2010, the Board approved the aforementioned policy and the following language in the Status 1B section of Policy 3.7.3.

> 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.

The interim policy is comparable to the Status 1A and 1B policies for candidates with VADs. If the outpatient candidate experiences a complication or infection due to the TAH or the driver, criterion (b) in Policy 3.7.3 allows this candidate to be classified as Status 1A; inpatient status is not required for this criterion.

On October 29, 2010, the Thoracic Committee voted in favor of the proposed interim policy: 18-supported; 0-opposed; and, 1-abstained. The interim policy will expire on December 1, 2011. On December 16, 2010, the Executive Committee of the Board supported this expiration date: 33-supported; 0-opposed; and 1-abstained.

In 2011, the Thoracic Committee began deliberating on a long-term policy for candidates with TAHs; and, it anticipates submitting the resulting policy for public comment this year.

Supporting Evidence:

Copeland et al. reported on the outcome of SynCardia's clinical trial with its temporary TAH; this clinical trial occurred from 1993 to 2002.[1] During the clinical trial, SynCardia observed that 79% of its study's patients survived to receive a heart transplant after implantation of the TAH.[1]

OPTN data as of October 7, 2010 indicated that there were 49 adult, inpatient heart transplant candidates with TAHs between January, 2009 and July, 2010. As of October 1, 2010, there were six heart transplant waiting list registrations for five candidates reported to have TAHs.

[E] http://www.clinicaltrials.gov/ct2/show/NCT00733447?term=syncardia&rank=2

Between January, 2009 and July, 2010, 42 of the 49 aforementioned candidates received heart transplants, two died, and two were removed from the waiting list because they were too sick. As there is no mechanism for centers to report candidates who received TAHs while inactive on the waiting list and who subsequently died, these data may underestimate the number of candidates with TAHs who died on the waiting list.

According to the OPTN data described above, of the more than 2,000 adult heart candidates waiting for transplants during January, 2009 and July, 2010, a very small number were candidates implanted with TAHs – these candidates were inpatients. The OPTN only began collecting data on outpatient candidates implanted with TAHs in November, 2010. As can be interpreted from the study by Copeland et al. as well as based on OPTN data, majority of the candidates with TAHs implanted survive to receive transplants. However, these inpatient candidates with TAHs have always received the high medical urgency status of 1A for transplant. And, it is too early to assess the rate of transplant for outpatient candidates with TAHs classified as Status 1B.

Expected Impact on Living Donors or Living Donation:

Not applicable to this proposal.

Expected Impact on Specific Patient Populations:

The proposed policy applies to adult outpatient candidates with TAHs.

Strengths and Weaknesses of the Proposed Policy:

The interim policy allows outpatient candidates implanted with TAHs to remain at Status 1A for 30 days at any point in time after discharge from the hospital, providing them some equal treatment with inpatient candidates with TAHs. If these outpatient candidates experience device-related complications or infections, they qualify for Status 1A by criterion (b) – hospitalization is not a requirement.

It can be argued that the interim policy considers the experimental nature of the TAH's portable driver in classifying the medical urgency status of outpatient candidates with TAHs. Current VAD policy does not accommodate the experimental nature of VADs or experimental nature of pumps for FDA-approved VADs. Without evidence on the success or failure of the portable driver, it is possible that the proposed 30 days of Status 1A for outpatient candidates with TAHs may be insufficient or excessive. If the latter were to be true, then the proposed policy may disadvantage those candidates whose time waiting at Status 1A is less than some outpatient candidates with TAHs, e.g., candidates with VADs. Candidates with VADs (left VAD (LVAD), right VAD (RVAD), and LVAD and RVAD (Bi-VAD)) will continue to receive only 30 days of Status 1A time, unless they qualify for Status 1A by criterion (b). Outpatient candidates implanted with TAHs will not only receive the 30 days of Status 1A time, but could also have received one or more 14-day periods of time at Status 1A prior to their discharge.

The interim policy allows for data to be collected on outpatient candidates implanted with TAHs. These data will inform the Thoracic Committee on modifications needed for a long-term TAH policy.

Implementation of the Interim Policy:

The interim policy makes use of the existing Status 1A VAD programming to allow UNet^{SM} to track the 30 days of Status 1A time automatically. This option is not ideal as it poses some data integrity issues. Other options also have data integrity issues but do not allow automatic tracking of the 30 days of Status 1A time. For example, allowing outpatient candidates with TAHs Status 1A time through the exception route or through criterion (a)(ii) – TAH – poses the following problem: UNet^{SM} only allows

inpatient candidates to receive Status 1A by exception or through criterion (a)(ii). This policy proposal addresses outpatient candidates; so, using either of these other options would force the user to report inpatient status inaccurately. Manual tracking of outpatient candidates with TAHs may seem feasible, but would require unknown resources to implement. Manual tracking is not necessary if these candidates are to be listed under the VAD criterion on the adult heart status 1A justification form.

Appendix A is the instructions for listing an outpatient candidate implanted with a TAH as Status 1A or 1B.

Adherence to the OPTN Final Rule:

The following construct in the OPTN Final Rule supports the proposed policy to enable an emerging category of candidate whose medical urgency may not be appropriately categorized in current policy.

> […]
> "121.8 Allocation of organs.
> (a) Policy development. […]
> (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
> (6) Shall be reviewed periodically and revised as appropriate;"
> […]

Plan for Evaluating the Proposed Policy:

In March and September of 2011, the Thoracic Committee will evaluate TAH data entered in the adult heart Status 1A and 1B justification forms.

Additional Data Collection:

The proposed policy modification will not require additional programming in UNet^{SM}.

Expected Implementation Plan:

UNOS implemented this interim policy immediately after its approval by the Board. The interim policy will expire on December 1, 2011.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audiences**	**Deliver Method**	**Timeframe**
Policy Notice	• Adult Outpatient TAH Candidates • General Public • Other Heart Transplant Candidates • Transplant Administrators • Transplant Coordinators • Transplant Physicians • Transplant Surgeons • Transplant Program Directors	Email	Was submitted immediately after and 30 days after approval by the Board of Directors

User manual on how to enter data in UNet[SM] for outpatient candidates with TAHs	• Transplant Administrators • Transplant Coordinators • Transplant Physicians • Transplant Surgeons • Transplant Program Directors	Email	Was distributed immediately after approval by the Board of Directors
Public comment	• Transplant Administrators • Transplant Coordinators • Transplant Physicians • Transplant Surgeons • Transplant Program Directors	Email (tah@unos.org)	Created and distributed within one month after the Board of Directors' meeting to garner feedback in advance of the March, 2011 public comment cycle
Public comment	• Public comment distribution list	Posted to the OPTN website on March 11, 2011 Presentation at regional meetings	March 11, 2011 through June 10, 2011

Monitoring and Evaluation:

The Department of Evaluation and Quality (DEQ) will continue to review heart Status 1A and 1B justification forms during site surveys. This proposal will automate approval of Status 1B-other forms for outpatient candidates with TAHs.

Policy Proposal:

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.]

Work Cited

1. Copeland, J.G., Smith, R.G., Arabia, F.A., Nolan, P.E., Sethi, G.K., Tsau, P.H., McClellan, D., & Slepian, M.J. (2004). Cardiac Replacement with a Total Artificial Heart as a Bridge to Transplantation. *New England Journal of Medicine, 351(9), 859-867.*