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MEMORANDUM

To: Thoracic Transplant Clinicians

From: Steven A. Webber, MD, MBChB, MRCP
Chair, Thoracic Organ Transplantation Committee

Re: Policy 3.7.3 - Status 1A for Outpatient Total Artificial Heart (TAH) Candidates – Will Expire on December 1, 2012

Date: October 10, 2012

The Thoracic Organ Transplantation Committee offers the following announcement to transplant programs with adult heart candidates implanted with total artificial hearts:

The temporary provision of Policy 3.7.3, granting adult heart transplant candidates implanted with a total artificial heart (TAH) that are discharged from the listing hospital 30 days of Status 1A time at any point after discharge, is due to expire on December 1, 2012. After reviewing data collected since the implementation of the policy in November, 2010, the Thoracic Organ Transplantation Committee unanimously voted to allow the policy to expire.

Any unused Status 1A time available pursuant to this provision will not carry over past December 1, 2012. Additionally, the provision permitting outpatient candidates implanted with a TAH to be registered as Status 1B at any time after discharge will also expire.

However, candidates implanted with a TAH will still be eligible to be registered as Status 1A if they fulfill the policy requirements for Status 1A(a)(ii) or Status 1A(b). Transplant programs may also request a Status 1B exception for outpatient candidates implanted with TAH.

As of December 1, 2012, Policy 3.7.3 will read as follows:

Language that is proposed for removal is struck through (~~example~~).

3.7.3 Adult Candidate Status. Each candidate awaiting heart transplantation receives a status code corresponding to the candidate's medical urgency for transplant. A heart transplant candidate at least 18 years of age at the time of listing receives a status code as follows:

Status	Definition
Status 1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for a 1A(b) candidate) 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.]~~

NOTE: The above language (in brackets) will expire on December 1, 2012.

[There are no further changes until Policy 3.7.3 Status 1B]

Status 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.]~~

NOTE: The above language (in brackets) will expire on December 1,

2012.

Status 1B by Exception

A candidate who does not meet the criteria for Status 1B may nevertheless be listed as Status 1B upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other Status 1B candidates. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it shall be



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forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form

A completed Heart Status 1B Justification Form must be submitted to UNetSM in order to list a candidate as Status 1B.

[There are no further changes to Policy 3.7.3]

Please click on the link below to read the policy on adult heart allocation – Policy 3.7.3 (Adult Candidate Status) – and other thoracic policies:

http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_9.pdf

If you have questions, please contact your regional administrator at 804-782-4800.

Thank you.