

Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNetSM a Change in Criterion or Status within Twenty-Four Hours

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policies Affected: Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status)

Distributed for Public Comment: September 2011

Amended After Public Comment: No

Effective Date: Changes to Policy 3.7.4 Status 1A criterion (e) and Status 1B criterion (a) will be implemented and effective pending programming. The remaining changes will be effective September 1, 2012.

Problem Statement
As part of its site audit criteria, the OPTN Contractor requires adult and pediatric heart transplant programs to record in UNet SM any changes to a candidate's status or criterion within 24 hours of that change. This requirement is not in policy.

Changes
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet SM within 24 hours of the change in medical condition.
The OPTN Contractor will change the pediatric heart status justification form to display each inotrope and its dosage that meet Status 1A criterion (e) and Status 1B criterion (a) in Policy 3.7.4.

Action Required
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must <i>continue to</i> report the accurate information in UNet SM within 24 hours of the change in medical condition.
The OPTN Contractor will send a system notice when the changes to Policy 3.7.4 Status 1A criterion (e) and Status 1B criterion (a) have been programmed in UNet SM .

Affected Policy Language:

3.7.3 Adult Candidate Status.— Each candidate awaiting heart transplantation is ~~assigned~~receives a status code ~~which corresponds~~ corresponding to ~~how medically urgent it is that the candidate's medical urgency~~ receive afor 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~~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) 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.

- (b) Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an “other” complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion 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.

- (c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion 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.
- (d) Continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

Status 1A by-Exception

A candidate who does not meet ~~criteria~~criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify~~and justification~~ to the applicable Regional Review Board ~~that why~~ the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of~~as other candidates in Status 1A~~this status as defined above~~. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A~~the status criteria~~. The justification must be reviewed and approved by the Regional Review Board. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. ~~A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status.~~

A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing ~~under this criterion~~ by exception requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is

not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~ The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1A Justification Form

A completed Heart Status 1A Justification Form must be submitted to ~~in~~ UNetSM in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B ~~unless the attending physician recertifies the candidate's qualification for a Status 1A criterion. Note: This automatic downgrade will not require submission of a Status 1B Justification Form.~~ The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or 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.

Status 1B- by Exception

A candidate who does not meet the criteria for Status 1B may nevertheless be ~~assigned to such status~~ listed as Status 1B upon application by his or her transplant physician. ~~The transplant physician must and justification justify~~ to the applicable Regional Review Board that why the candidate is considered, using ~~accepted acceptable~~ accepted acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of as other Status 1B candidates in this status as defined above.~~ The justification must include a rationale for incorporating the exceptional case as part of ~~Status 1B the status criteria.~~ A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~ 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~~ in UNetSM in order to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility

If a change in the candidate’s medical condition makes the criterion used to justify a candidate’s Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNetSM within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

3.7.4 Pediatric Candidate Status. Each candidate awaiting heart transplantation ~~is assigned~~ receives a status code ~~which corresponds~~ corresponding to ~~how medically urgent it is~~ that the candidate’s medical urgency for ~~receive~~ a transplant. Medical urgency is assigned to a heart transplant candidate who is ~~less than 18 years of age at the time of listing as follows:~~ Pediatric heart transplant candidates who have not received a heart transplant remain on the Waiting List at the time of ~~before~~ their 18th birthday ~~without receiving a transplant,~~ shall continue to qualify for medical urgency status based ~~upon~~ the criteria set forth in on Policy 3.7.4. A heart transplant candidate who is less than 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 meets at least one of the following criteria:

- (a) Requires assistance with a ventilator;
- (b) Requires assistance with a mechanical assist device (e.g., ECMO);
- (c) Requires assistance with a balloon pump;

- (d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;
- (e) Requires infusion of high dose ~~(e.g., dobutamine > / = 7.5 mcg/kg/min or milrinone > / = .50 mcg/kg/min)~~ or multiple inotropes ~~(e.g., addition of dopamine at > / = 5 mcg/kg/min)~~ (The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.); or,
- (f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be 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.

Qualification for Status 1A under criteria (a) through (e) 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.

Submission of Status 1A Justification Form

~~For all pediatric candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received on UNetSM in order to list a candidate As as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. Candidates who are listed as Status 1A will automatically revert back to Status 1B after 14 days unless these candidates are re-listed on UNetSM as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above~~

A completed Heart Status 1A Justification Form must be submitted in UNetSM in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B

A candidate listed as Status 1B meets at least one of the following criteria:

- (a) Requires infusion of low dose single inotropes ~~(e.g., dobutamine or dopamine < / =7.5 mcg/kg/min)~~(The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);
- (b) Less than six months old and does not meet the criteria for Status 1A; or
- (c) Growth failure *i.e.*, +less than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5th percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. –Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate's growth at two different times, second, calculating the candidate's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.*, (candidate's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

Status 1B by Exception

A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. 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 forwarded for review by the Thoracic Organ Transplantation Committees. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

~~For all pediatric candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNetSM in order to list a candidate as Status 1B. A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~

Submission of Status 1B Justification Form

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

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNetSM within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select “Policies” from the “I am looking for:” box in the upper left hand corner. From the OPTN website, select the “Policy Management” tab, then select “Policies.”