

3.7 **ALLOCATION OF THORACIC ORGANS.** This policy describes how thoracic organs (hearts, heart-lung combinations, single and double lungs) are to be allocated to candidates awaiting a thoracic organ transplant.

3.7.1 **Exceptions.** Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances)), and 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

3.7.1.1 **Exception for Sensitized Candidates.** The transplant surgeon or physician for a candidate awaiting thoracic organ transplantation may determine that the candidate is "sensitized" such that the candidate's antibodies would react adversely to certain donor cell antigens. It is permissible not to use the allocation policies set forth in Policy 3.7 for allocation of a particular thoracic organ when all thoracic organ transplant centers within an OPO and the OPO agree to allocate the thoracic organ to a sensitized candidate because results of a crossmatch between the blood serum of that candidate and cells of the thoracic organ donor are negative (i.e., the candidate and thoracic organ donor are compatible). The level of sensitization at which a candidate may qualify for this exception is left to the discretion of the listing transplant center, and subject to agreement among all thoracic organ transplant centers within an OPO and the OPO. Sensitization is not a qualifying criterion for assigning a candidate to a heart status category as described in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status).

3.7.2 **Geographic Sequence of Thoracic Organ Allocation.** Thoracic organs are to be allocated locally first, then within the following zones in the sequence described in Policy 3.7.10 and Policy 3.7.11. Five zones will be delineated by concentric circles of 500, 1,000, and 1,500 and 2,500 nautical mile radii with the donor hospital at the center. Zone A will extend to all transplant centers which are within 500 miles from the donor hospital but which are not in the local area of the donor hospital. Zone B will extend to all transplant centers that are at least 500 miles from the donor hospital but not more than 1,000 miles from the donor hospital. Zone C will extend to all transplant centers that are at least 1,000 miles from the donor hospital but not more than 1,500 miles from the donor hospital. Zone D will extend to all transplant centers that are located beyond 1,500 miles from the donor hospital, but not more than 2,500 miles from the donor hospital. Zone E will extend to all transplant centers that are located beyond 2,500 miles from the donor hospital.

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

IA 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

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- 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.

- (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 (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 (e.g., dobutamine  $\geq 7.5$  mcg/kg/min, or milrinone  $\geq .50$  mcg/kg/min), 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.

A candidate who does not meet the criteria for Status 1A 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 acceptable 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. The justification must be reviewed and approved by the Regional Review. 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 to for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. A candidate's listing under this exceptional provision is valid for 14 days.

Any further extension of the Status 1A listing under this criterion 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.

For all adult candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received by on UNet<sup>SM</sup> in order to list a candidate

as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.3. Candidates listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNet<sup>SM</sup> by an attending physician within the time frames described in the definitions of status 1A(a)-(d) above.

- 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.

For all adult candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate within one working day of a candidate's listing 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.

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

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

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 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 less than 18 years of age at the time of listing as follows: Pediatric heart transplant candidates who remain on the Waiting List at the time of their 18<sup>th</sup> birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in Policy 3.7.4.

Status Definition

- 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  $\geq 7.5$  mcg/kg/min or milrinone  $\geq 50$  mcg/kg/min) or multiple inotropes (*e.g.*, addition of dopamine at  $\geq 5$  mcg/kg/min); 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.

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.

For all pediatric candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate 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 UNet<sup>SM</sup> as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above

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  $\leq 7.5$  mcg/kg/min);
- (b) Less than six months old and does not meet the criteria for Status 1A; or
- (c) Growth failure *i.e.*,  $+5^{\text{th}}$  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  $<5^{\text{th}}$  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).

For all pediatric candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNet<sup>SM</sup> 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.

- 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.
- 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

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.

**3.7.5 Allocation of Pediatric Donor Hearts to Pediatric Heart Candidates.** Within each heart status, a heart retrieved from a pediatric organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, a pediatric organ donor is defined as an individual who is less than 18 years of age.

**3.7.6 Lung Allocation.** Candidates are assigned priority in lung allocation as follows:

**3.7.6.1 Candidates Age 12 and Older.** Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.

**Table 1**  
**Factors Used to Predict Risk of Death on the Lung Transplant Waitlist**

1.	Forced vital capacity (FVC)
2.	Pulmonary artery (PA) systolic pressure (Groups A, C, and D <sup>+</sup> – see 3.7.6.1.a)
3.	O <sub>2</sub> required at rest (Groups A, C, and D <sup>+</sup> – see 3.7.6.1.a)
4.	Age
5.	Body mass index (BMI)
6.	Diabetes
7.	Functional Status
8.	Six-minute walk distance
9.	Continuous mechanical ventilation
10.	Diagnosis
11.	PCO <sub>2</sub> (see 3.7.6.1.b) <u>Bilirubin (current bilirubin – all <u>g</u>Groups; change in bilirubin –</u>
12.	<u>Group B; see 3.7.6.1.c)</u>

**Table 2**  
**Factors that Predict Survival after Lung Transplant**

1.	FVC (Groups B and D – see 3.7.6.1.a)
2.	PCW pressure $\geq 20$ (Group D – see 3.7.6.1.a)
3.	Continuous mechanical ventilation
4.	Age
5.	Serum Creatinine
6.	Functional Status
7.	Diagnosis

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.

As an example, assume that a donor lung is available, and both Candidate X and Candidate Y are on the Waiting List. Taking into account all diagnostic and prognostic factors, Candidate X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Candidate X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Candidate Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize candidates based on the difference between each candidate’s transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

**Table 3**  
**Example Illustrating the LAS Calculation**

Parts of the Score Equation	Candidate X	Candidate Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
<b>e. Lung Allocation Score</b>	<b>74.3</b>	<b>78.0</b>

In the example here, Candidate X's raw allocation score would be 84.1 and Candidate Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by candidates and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Candidate X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Candidate Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Candidate Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Candidate X.

a. Lung Disease Diagnosis Groups

The following are some of the diagnoses included in groups A, B, C, and D.

(i) *Group A*

Includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure  $\leq 30$  mmHg

(ii) *Group B*

Includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases

(iii) *Group C*

Includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia

(iv) *Group D*

Includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure  $> 30$  mmHg, and obliterative bronchiolitis (non-retransplant)

b. PCO<sub>2</sub> in the Lung Allocation Score

UNet<sup>SM</sup> will use two measures of PCO<sub>2</sub> in a candidate's lung allocation score calculation: current PCO<sub>2</sub>, and change in PCO<sub>2</sub>. There are two types of PCO<sub>2</sub> change calculations: "threshold change" and "threshold change maintenance." The following explanations (i-vi) and illustrations (Figures 1-3) detail how UNet<sup>SM</sup> uses PCO<sub>2</sub> in the lung allocation score.

(i) *Use of Arterial, Venous, or Capillary PCO<sub>2</sub> Values*

In UNet<sup>SM</sup>, a center may enter a PCO<sub>2</sub> value from an arterial, venous, or capillary blood gas test. UNet<sup>SM</sup> will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNet<sup>SM</sup> will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNet<sup>SM</sup> will use the PCO<sub>2</sub> value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet<sup>SM</sup> will use the arterial value in the lung allocation score calculation.

(ii) *Definition of Current PCO<sub>2</sub>*

Current PCO<sub>2</sub> is the PCO<sub>2</sub> value with the most recent test date entered in UNet<sup>SM</sup>.

(iii) *Expiration of Current PCO<sub>2</sub> Value*

UNet<sup>SM</sup> will evaluate a current PCO<sub>2</sub> value as expired according to Policy 3.7.6.3.2.

(iv) *Use of Normal Clinical Value for Current PCO<sub>2</sub>*

The normal clinical value of PCO<sub>2</sub> is 40 mmHg. UNet<sup>SM</sup> will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO<sub>2</sub> is less than 40 mmHg, missing, or expired.

(v) *PCO<sub>2</sub> Values Used in the Change Calculations*

There are two types of PCO<sub>2</sub> change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO<sub>2</sub> change is 15% or higher. In this calculation, UNet<sup>SM</sup> will use highest and lowest values of PCO<sub>2</sub>. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet<sup>SM</sup> will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet<sup>SM</sup> will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is  $[(\text{highest PCO}_2 - \text{lowest PCO}_2) / \text{lowest PCO}_2]$

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO<sub>2</sub> value must be at least 15% higher than the lowest value used in the threshold change



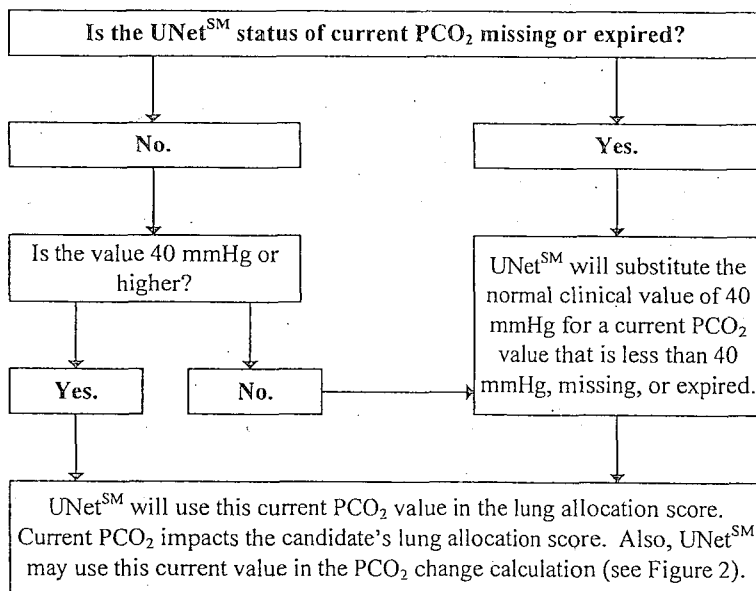
calculation. The equation for threshold change maintenance is  $[(\text{current PCO}_2 - \text{lowest PCO}_2) / \text{lowest PCO}_2]$ .

UNet<sup>SM</sup> will perform the threshold change maintenance calculation either when the current PCO<sub>2</sub> value expires (Policy 3.7.6.3.2) or a new current PCO<sub>2</sub> value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO<sub>2</sub> value can be the highest one that was used in the threshold change calculation. If a current PCO<sub>2</sub> value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO<sub>2</sub> value expires, UNet<sup>SM</sup> will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% higher than the lowest value in the threshold change calculation.

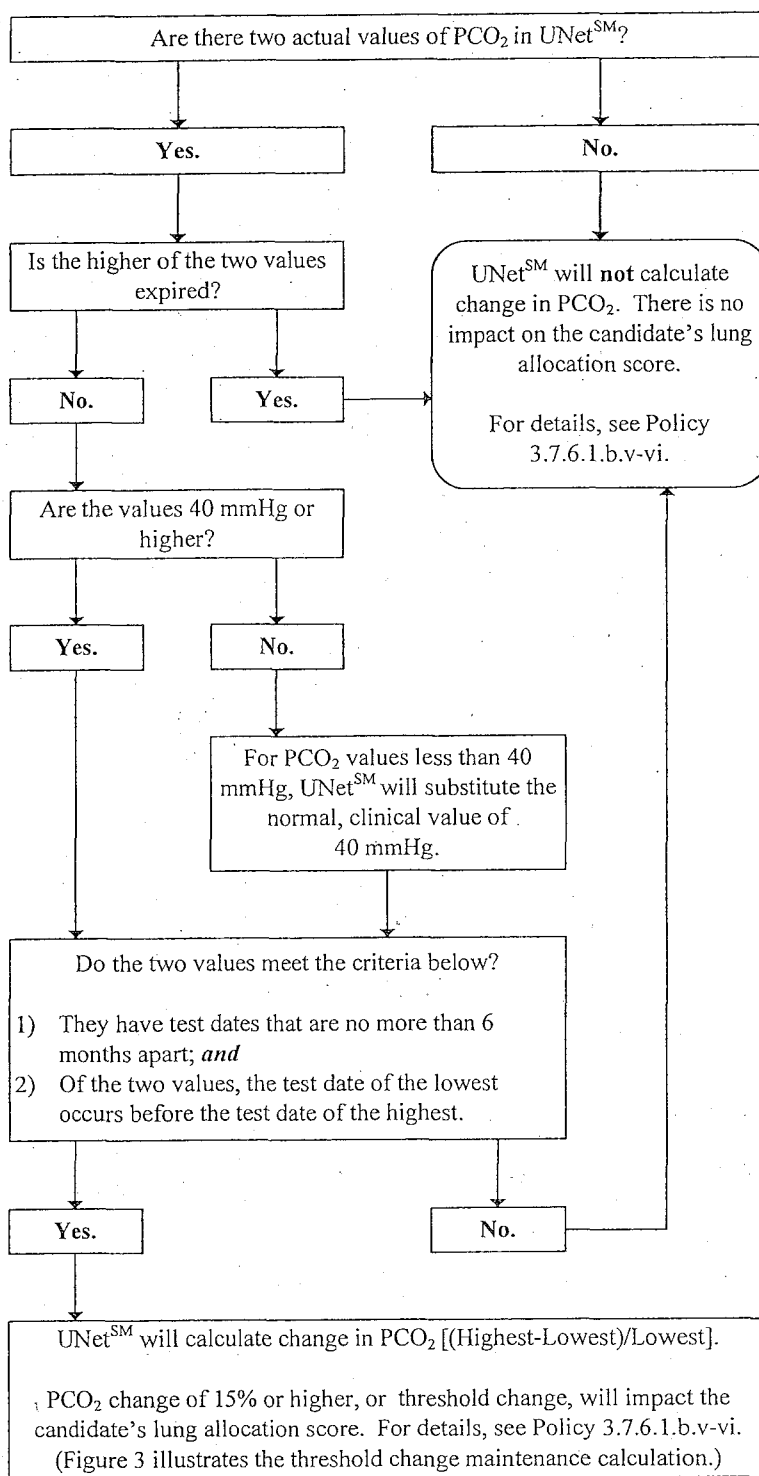
If a center enters a new current PCO<sub>2</sub> value for a candidate who has lost the impact from threshold change, UNet<sup>SM</sup> will perform the threshold change maintenance calculation. If the new current PCO<sub>2</sub> value is at least 15% higher than the lowest value used in the threshold change calculation, UNet<sup>SM</sup> will *reapply* the impact from threshold change to the candidate's lung allocation score.

- (vi) *Impact of PCO<sub>2</sub> Threshold Change in the Lung Allocation Score*  
A change in PCO<sub>2</sub> that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO<sub>2</sub> is at least 15% higher than the lowest value used in the threshold change calculation.

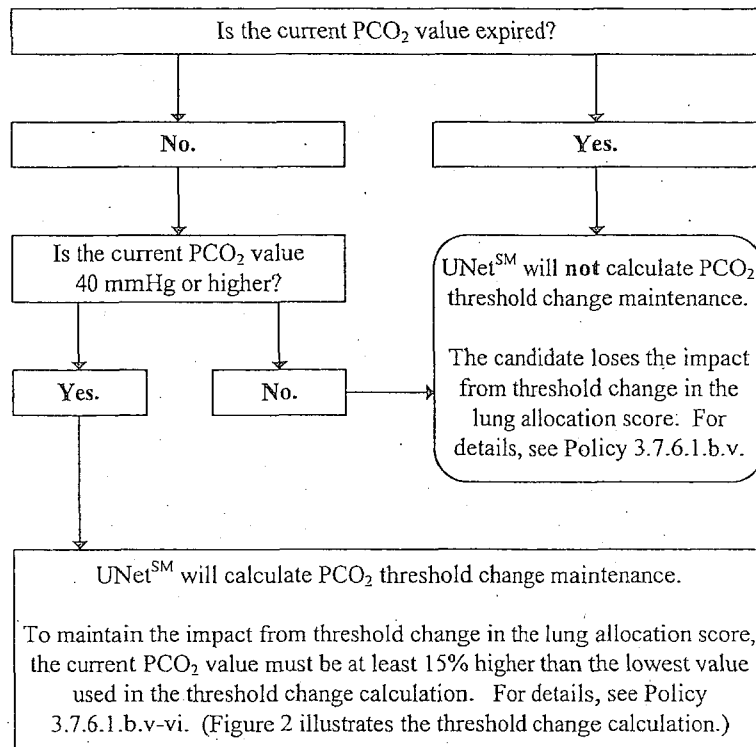
**Figure 1**  
**Use of Current PCO<sub>2</sub> in the Lung Allocation Score**



**Figure 2**  
**PCO<sub>2</sub> Threshold Change Calculation**



**Figure 3**  
**PCO<sub>2</sub> Threshold Change Maintenance Calculation**



c. Bilirubin in the Lung Allocation Score

UNet<sup>SM</sup> will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNet<sup>SM</sup> uses bilirubin in the lung allocation score.

(i) Definition of Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet<sup>SM</sup>. UNet<sup>SM</sup> will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

(ii) Expiration of Current Bilirubin Value

UNet<sup>SM</sup> will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.2.

(iii) Use of Normal Clinical Value for Current Bilirubin

The normal clinical value of current bilirubin is 0.7 mg/dL. UNet<sup>SM</sup> will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

(iv) Bilirubin Values Used in the Change Calculations (Group B Only)

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet<sup>SM</sup> will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet<sup>SM</sup> will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet<sup>SM</sup> will substitute the normal clinical value of 0.7 mg/dL, before calculating change. The equation for threshold change is [(highest bilirubin – lowest bilirubin)/lowest bilirubin].

The threshold change maintenance calculation occurs after the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is [(current bilirubin – lowest bilirubin)/lowest bilirubin].

UNet<sup>SM</sup> will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3.2) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet<sup>SM</sup> will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% higher than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNet<sup>SM</sup> will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the threshold change calculation, UNet<sup>SM</sup> will *reapply* the impact from threshold change to the candidate's lung allocation score.

(v) *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*

A change in bilirubin that is 50% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

**NOTE:** *The amendments to Policy 3.7.6.1.c (Bilirubin in the Lung Allocation Score) shall be implemented pending Executive Committee approval of the related implementation plan. (Approved at the June 2009 Board of Directors Meeting.)*

**3.7.6.2 Candidates Age 0 - 11.** Candidates 0 – 11 years old are assigned priority for lung offers based upon waiting time, according to the status categories UNet<sup>SM</sup> ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each status priority, UNet<sup>SM</sup> will rank

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candidates will be ranked by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority Status 1, UNet<sup>SM</sup> will only consider the most current period of time a candidate has spent as Priority 1, i.e. UNet<sup>SM</sup> will not tally the time waiting during multiple Priority 1 periods. candidates will be ranked in descending order according to the length of time waiting at that status. For Priority Status 2 candidates, and if there is ever a tie among Priority 1 candidates, UNet<sup>SM</sup> will use these candidates' total waiting time to determine the order for receiving lung offers. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive. total active waiting time (defined for this purpose as beginning when the candidate was added to the waiting list and ending when the lung match run was generated) will be used to rank candidates on the match run.

A program may update clinical data used to justify a candidate's status priority may be updated at any time a program it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a programs must update every candidate variable each qualifying criterion, except those candidate variables that which is are obtained only by heart catheterization, for Status 1 candidates, at least once every in each six months period following the candidate's registration after initial listing on the lung waiting list Waitlist<sup>SM</sup>. If at any time, more than six months have elapsed since the last six month "anniversary" date of the candidate's initial listing without an update, without data updates after the candidate's last six-month "anniversary" of his or her Waitlist<sup>SM</sup> registration, then the candidate's status Priority 1 will automatically revert to Status Priority 2. UNet<sup>SM</sup> will assess the currency of lung variables for each candidate on every six-month "anniversary" date. (For example, if a candidate is first registered on the Waitlist<sup>SM</sup> on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet<sup>SM</sup> will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet<sup>SM</sup> will reassess the currency of the lung variables on July 1, 2012, and then any variables with test dates that are on or after January 1, 2012 would be considered current.)

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total waiting time is the amount of time spent waiting as a Status 1 and Status 2.

**Status Priority 1:** Candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous mechanical ventilation; *or*,
  - Requiring supplemental oxygen delivered by any means to achieve  $FiO_2$  greater than 50% in order to maintain oxygen saturation levels greater than 90%; *or*,
  - Having an arterial or capillary  $PCO_2$  greater than 50 mmHg, or a venous  $PCO_2$  greater than 56mmHg.
  
- **Pulmonary hypertension, defined as:**
  - Having pulmonary vein stenosis involving 3 or more vessels; *or*
  - Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M<sup>2</sup>, recurrent syncope, or hemoptysis

Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet<sup>SM</sup>. Transplant centers must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit

~~an exception request to the Lung Review Board for prospective consideration, as described below.~~

~~or~~

~~o Having pulmonary vein stenosis involving 3 or more vessels.~~

• ~~Exceptional cases by prospective submission to~~ **An exception case approved by the Lung Review Board;**

o In its review of exception requests, the Lung Review Board will follow the prospective review process described in Policy 3.7.6.4 (Lung Candidates with Exceptional Cases).

**Status 2:** Candidates who do not meet the criteria for ~~Status Priority 1~~ must be listed ~~Status~~ as Priority 2.

*NOTE: The amendments to Policy 3.7.6.2 (Candidates Age 0-11) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Double lines and double strikeouts were added and approved at the June 23, 2009 Board of Directors Meeting.)*

*NOTE: The amendments to Policy 3.7.6.2 (Candidates Age 0-11) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Approved at the June 20, 2008 Board of Directors Meeting.)*

**3.7.6.3 Candidate Variables in UNet<sup>SM</sup>.** Entry into UNet<sup>SM</sup> of candidate clinical data responding to the variables shown in Tables 1 and 2 above, as they may be amended from time to time, is required when listing a candidate for lung transplantation. Diagnosis, birthdate (used to calculate age), height, and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a Lung Allocation Score of zero, if the Functional Status class or assisted ventilation variable is missing at any time. If pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for the missing pulmonary pressure variable. (A default value of 20 mm/Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm/Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm/Hg will be assigned for missing pulmonary artery mean pressure.) The default values for pulmonary pressures will also be used in the calculation of Lung Allocation Scores for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), will be selected for the candidate. Programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board to determine whether the estimated values are appropriate and whether further action is warranted. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to the procedures set forth in Policy 3.7.6.4.

**3.7.6.3.1 Candidate Variables in UNet<sup>SM</sup> upon Implementation of Lung Allocation Scores Described in Policy 3.7.6.** Candidates registered on the Lung Waiting List at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 with no or incomplete clinical data will receive the Least Beneficial Value or the default pulmonary pressure value for each incomplete variable or a Lung Allocation Score of zero, as described in Policy 3.7.6 above.

**3.7.6.3.2 Updating Candidate Variables.** Programs may update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update every candidate variable, except those candidate variables that are obtainable only by heart catheterization, for each candidate at least once every six months beginning on the date of initial listing on the lung waitlist. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing, without an update, then the variable will be considered expired. (For example, if a candidate was first registered on the waitlist on January 1, 2005, and the most recent six-month "anniversary" is January 1, 2006, then any variables older than July 1, 2005, will be considered expired.)

If the Functional Status or assisted ventilation variable is expired, then the candidate will receive a Lung Allocation Score of zero. If any other candidate variable, excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure, is expired, then the candidate will receive the Least Beneficial Value for that variable. The frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) will be left to the discretion of the transplant center. Actual values or estimated values for pulmonary pressures will be valid until they are either updated with a new actual value or a new estimated value is entered pursuant to Policy 3.7.6.4.

**3.7.6.4 Lung Candidates With Exceptional Cases.** Special cases require prospective review by the Lung Review Board. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant center will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to the OPTN contractor. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that the contractor sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the center may choose to appeal the decision for reconsideration by the Lung Review Board. The center will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that the contractor sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.

Should the Lung Review Board deny a transplant center's initial request or appealed request for an estimated value or a specific Lung Allocation Score, the transplant center has the option to override the decision of the LRB. If the transplant center elects to override the decision of the Lung Review Board, then the request or appeal will be automatically referred to the Thoracic Organ Transplantation Committee for review; this review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

Estimated values will remain valid until an actual value is entered in the system or a new estimated value is entered pursuant to the procedures described in this

policy. A diagnosis that has been approved by the Lung Review Board or the Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. Lung Allocation Scores will remain valid for six (6) months from the entry date (or the candidate's twelfth birthday, whichever occurs later). If the candidate continues to be on the Waiting List six months after the entry date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is entered pursuant to the procedures described in this policy or the center chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung Review Board.

**3.7.7 Allocation of Thoracic Organs to Heart-Lung Candidates.** When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart. Heart-lung candidates shall use the ABO matching requirements described in Policy 3.7.8 when they are included in the heart match run results. Heart-lung candidates shall use the ABO matching requirements described in policy 3.7.8.2 when they are included in the lung match run results.

**3.7.8 ABO Typing for Heart Allocation.** Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

- (i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;
- (ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;
- (iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;
- (iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.
- (v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.
- (vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

- (i) Candidate is *in utero*;
- (ii) Candidate is less than 1 year of age, and meets all of the following:
  - a. Listed at Status 1A or 1B, and

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November 17, 2009