

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

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.]

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

- (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-Exception

A candidate who does not meet criteria (a), (b), (c), or (d) may nevertheless be classified as Status 1A upon application by his or her transplant physician 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 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 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 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. 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 1A Justification Form

A completed Heart Status 1A Justification Form must be submitted to 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 status downgrade will not require submission of a Status 1B Justification Form.

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-Exception

A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/or her transplant physician 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 to UNetSM in order to list a candidate as Status 1B.

- 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 18th 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 ≥ 7.5 mcg/kg/min or milrinone $\geq .50$ mcg/kg/min) or multiple inotropes (e.g., addition of dopamine at ≥ 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 UNetSM 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 UNetSM 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 $< / = 7.5$ 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 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.

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 ⁺ – see 3.7.6.1.a)
3. O ₂ required at rest (Groups A, C, and D ⁺ – 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 ₂ (see 3.7.6.1.b)
12. <u>Bilirubin (current bilirubin – all gGroups; change in bilirubin – 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
e. Lung Allocation Score	74.3	78.0

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, lymphangiioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 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. PCO₂ in the Lung Allocation Score

UNetSM will use two measures of PCO₂ in a candidate's lung allocation score calculation: current PCO₂, and change in PCO₂. There are two types of PCO₂ change calculations: "threshold change" and "threshold change maintenance." The following explanations (i-vi) and illustrations (Figures 1-3) detail how UNetSM uses PCO₂ in the lung allocation score.

(i) *Use of Arterial, Venous, or Capillary PCO₂ Values*

In UNetSM, a center may enter a PCO₂ value from an arterial, venous, or capillary blood gas test. UNetSM will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNetSM will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNetSM will use the PCO₂ 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, UNetSM will use the arterial value in the lung allocation score calculation.

(ii) *Definition of Current PCO₂*

Current PCO₂ is the PCO₂ value with the most recent test date entered in UNetSM.

(iii) *Expiration of Current PCO₂ Value*

UNetSM will evaluate a current PCO₂ value as expired according to Policy 3.7.6.3.2.

(iv) *Use of Normal Clinical Value for Current PCO₂*

The normal clinical value of PCO₂ is 40 mmHg. UNetSM will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO₂ is less than 40 mmHg, missing, or expired.

(v) *PCO₂ Values Used in the Change Calculations*

There are two types of PCO₂ change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO₂ change is 15% or higher. In this calculation, UNetSM will use highest and lowest values of PCO₂. 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, UNetSM will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNetSM will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is **[(highest PCO₂ – lowest PCO₂)/lowest PCO₂]**

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 PCO₂ value must be at least 15% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is **[(current PCO₂ – lowest PCO₂)/lowest PCO₂]**.

UNetSM will perform the threshold change maintenance calculation either when the current PCO₂ value expires (Policy 3.7.6.3.2) or a new current PCO₂ value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO₂ value can be the highest one that was used in the threshold change calculation. If a current PCO₂ 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 PCO₂ value expires, UNetSM 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 PCO₂ value for a candidate who has lost the impact from threshold change, UNetSM will perform the threshold change maintenance calculation. If the new current PCO₂ value is at least 15% higher than the lowest value used in the threshold change calculation, UNetSM will *reapply* the impact from threshold change to the candidate's lung allocation score.

- (vi) *Impact of PCO₂ Threshold Change in the Lung Allocation Score*
A change in PCO₂ 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 PCO₂ is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO₂ in the Lung Allocation Score

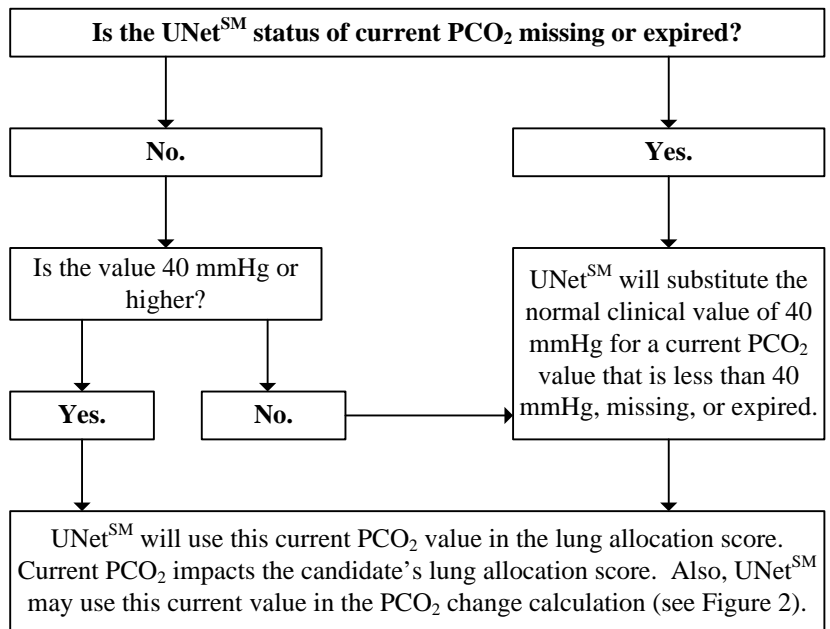
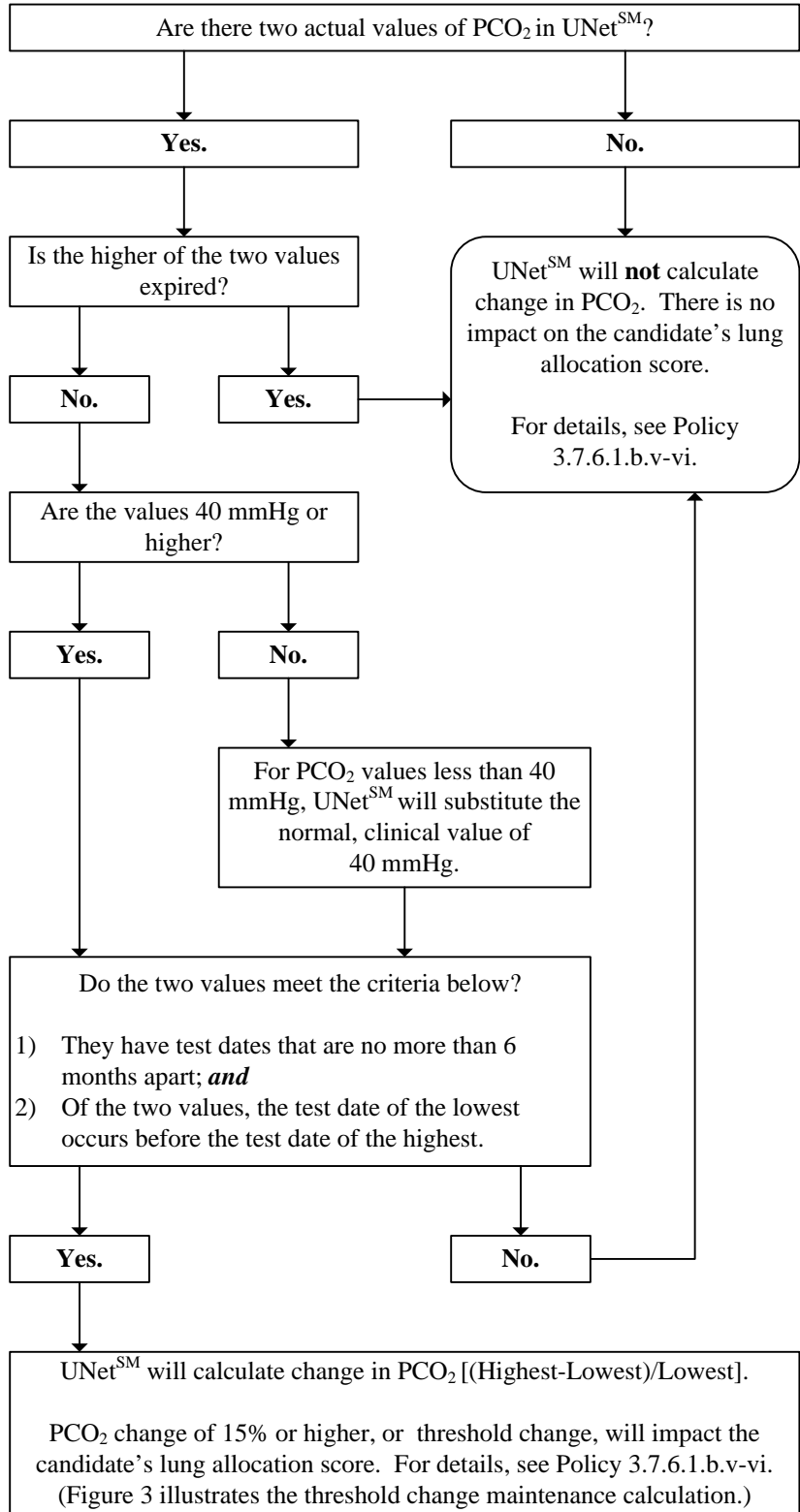


Figure 2
PCO₂ Threshold Change Calculation



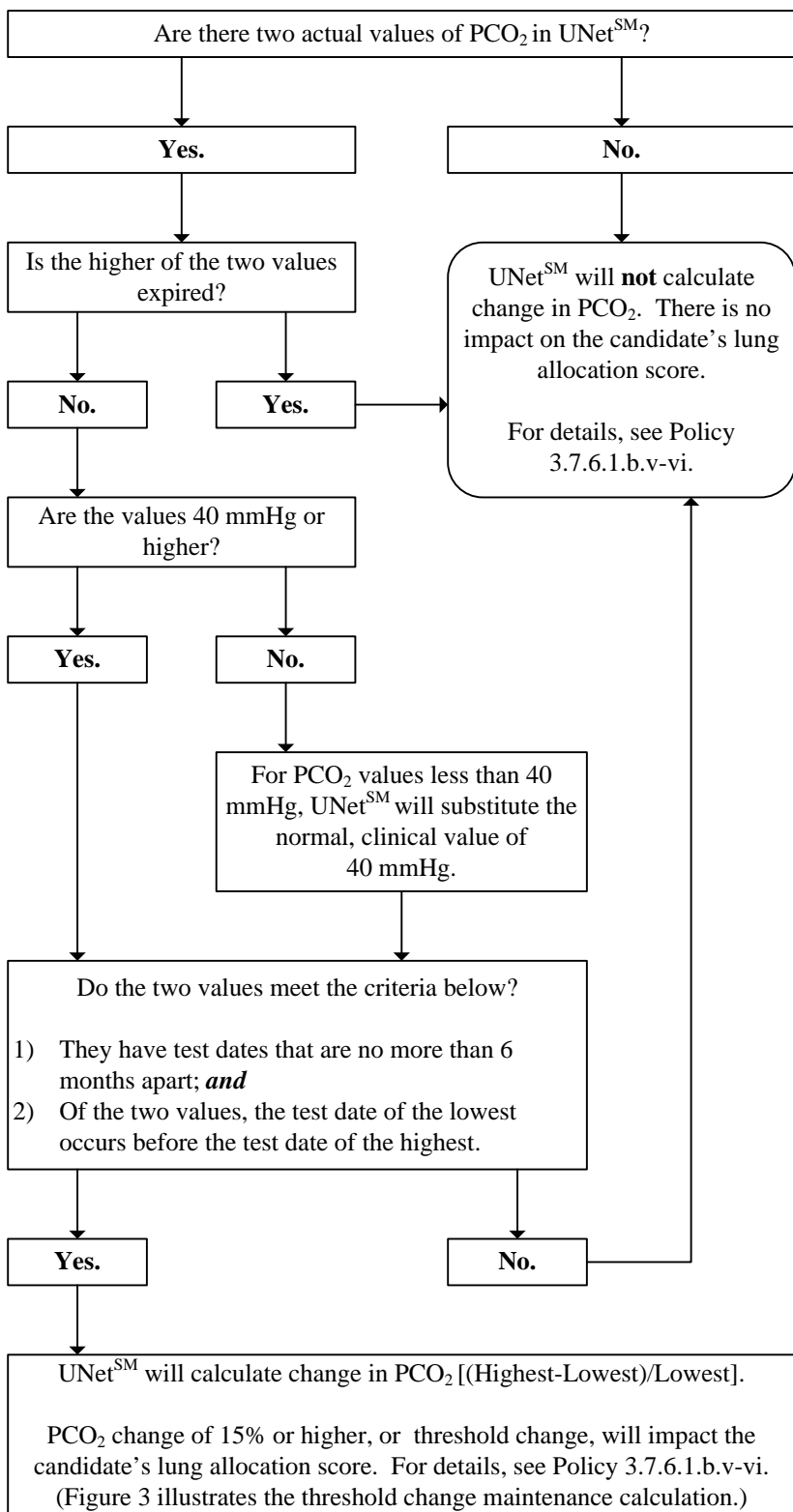
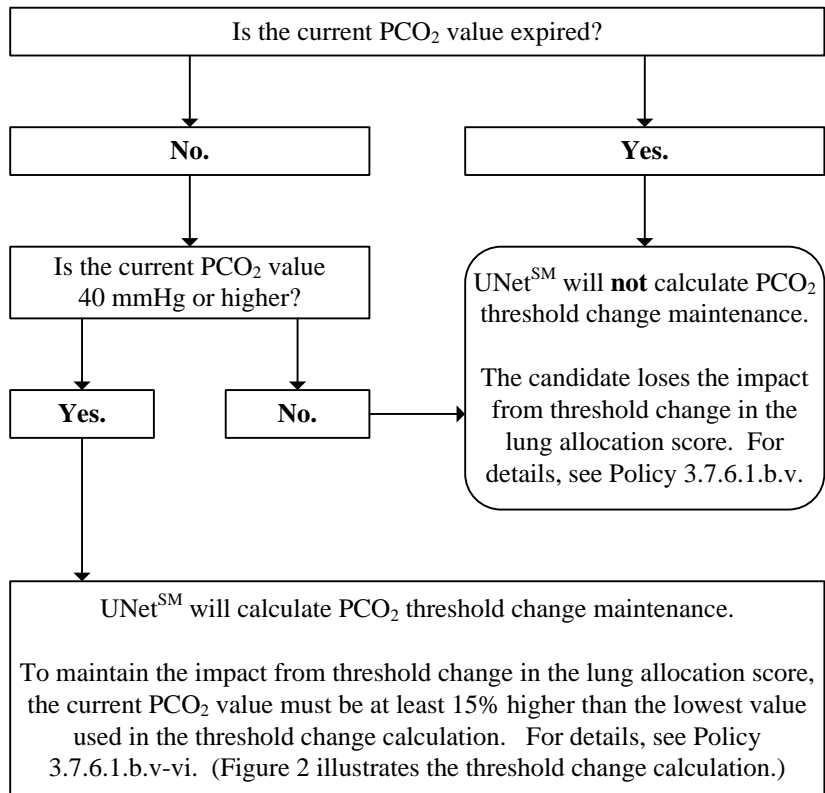


Figure 3
PCO₂ Threshold Change Maintenance Calculation



c. Bilirubin in the Lung Allocation Score

UNetSM 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 UNetSM 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 UNetSM. UNetSM 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

UNetSM 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. UNetSM 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, UNetSM 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, UNetSM will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNetSM 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].

UNetSM 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, UNetSM 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, UNetSM 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, UNetSM 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. UNetSM ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each priority, UNetSM will rank candidates by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority 1, UNetSM will only consider the most current period of time a candidate has spent as Priority 1, i.e., UNetSM will not tally the time waiting during multiple Priority 1 periods. For Priority 2, and if there is ever a tie among Priority 1 candidates, UNetSM 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.

A program may update clinical data used to justify a candidate's priority at any time it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a program must update each qualifying criterion, except that which is obtained only by heart catheterization, at least once in each six month period following the candidate's registration on the lung WaitlistSM. If more than six months elapse without data updates after the candidate's last six-month "anniversary" of his or her WaitlistSM registration, then the candidate's Priority 1 will revert to Priority 2. UNetSM 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 WaitlistSM on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNetSM will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNetSM 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.)

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 FiO₂ greater than 50% in order to maintain oxygen saturation levels greater than 90%; *or*,
 - Having an arterial or capillary PCO₂ greater than 50 mmHg, or a venous PCO₂ 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/M², syncope, or hemoptysis

Examples of accepted medical therapy for pulmonary hypertension will be listed in UNetSM. 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 as described below.

- **An exception case approved by the Lung Review Board:**
 - 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 Priority 1 must be listed as Priority 2.

3.7.6.3 Candidate Variables in UNetSM, Entry into UNetSM of candidate clinical data corresponding to the variables shown in Tables 1 and 2 in Policy 3.7.6.1 is required when listing a candidate for lung transplantation. Diagnosis, birth date (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 a value at any time.

If values for 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 these missing pulmonary pressure variables. 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. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to Policy 3.7.6.4.

3.7.6.3.1 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 each element of a candidate’s clinical data in UNetSM every six months, except those data obtainable only by heart catheterization. Also, as described further below, programs must update three clinical variables more frequently than six months for candidates with LAS of 50 or higher.

UNetSM defines a “six month anniversary date,” which first occurs six months from the date of initial listing, then every six months thereafter. UNetSM will consider a variable to be expired if the variable’s test date is six-months older than the most recent anniversary date.

If the test dates of the Functional Status or assisted ventilation variable expire, then the candidate’s Lung Allocation Score will be zero. If any other candidate variable expires - excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure- then the candidate will receive the Least Beneficial Value for that variable. The transplant center determines the frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) If a transplant center repeats a heart catheterization test, it must report the results in UNetSM.

UNetSM will consider actual values or estimated values for pulmonary pressures to be valid until the transplant center updates them with new actual values or new estimated values pursuant to Policy 3.7.6.4.

A program must update three key variables in UNetSM no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO₂. If a program does not perform a PCO₂ test in that time, then it does not need to update this value in UNetSM. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.

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
 - b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNetSM.
- (iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:
 - a. Is listed prior to age 2;
 - b. Is listed at Status 1A or 1B;
 - c. Has current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNetSM; and,
 - d. Has *not* received treatments within the prior 30 days that may have reduced titer values to 1:4 or less.

3.7.8.1 Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type. A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

Anti-A and/or Anti-B titers must be reported:

- (i) At time of listing (except for *in utero* candidates);
- (ii) Every 30 days after listing (**all** eligible born candidates);
- (iii) At transplant; and
- (iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts).

Listing and transplant outcomes for candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.

3.7.8.2 ABO Typing for Lung Allocation. Candidates who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated thoracic organs before candidates who have a compatible (but not identical) blood type with that of the donor and are awaiting an isolated lung transplant

3.7.9 Time Waiting for Thoracic Organ Candidates. Calculation of the time a candidate has been waiting for a thoracic organ transplant begins with the date and time the candidate is first registered as active on the Waiting List. Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age). When time waiting is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status/priority category. Where applicable, waiting time accrued by a candidate for a single thoracic organ transplant (heart or single lung) while waiting on the Waiting List also may be accrued for a second thoracic organ, when it is determined that the candidate requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a candidate for a multiple thoracic organ transplant while waiting on the Waiting List may be transferred to the Waiting List for a single thoracic organ transplant.

3.7.9.1 Waiting Time Accrual for Heart Candidates. Candidates listed as a Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation if the candidate is upgraded to a higher status. For example, a candidate who is listed as a Status 2 for 3 months and then is upgraded to a Status 1A for one week will accrue one week of waiting time as a Status 1A. If the candidate is downgraded to a Status 2 for another 3 weeks, then the candidate will have 4 months of total accrued time. If the candidate subsequently is upgraded for another week as a Status 1A, then the candidate's Status 1A waiting time will be 2 weeks.

3.7.9.2 Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6 ~~Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 and~~

~~thereafter will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued.~~

** **BOLD** language that appears in Policy 3.7.9.2 was approved by the Executive Committee on March 11, 2005, and was implemented on May 4, 2005.

In the event that multiple candidates receive identical computed Lung Allocation Scores greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each candidate's most recent update in UNetSM by the member, of variables used in calculation of the Lung Allocation Score. (For example, if Candidate A and Candidate B have an identical Lung Allocation Score and identical priority for a lung offer, and Candidate A's data variables were most recently updated by the transplant center on May 1, 2005, and Candidate B's data variables were most recently updated by the transplant center on June 1, 2005, then Candidate A would receive higher priority for the lung offer because his most recent data update by the transplant center occurred first and the same set of data variables has been used to calculate Candidate A's Lung Allocation Score for the longest amount of time.)

In the event that multiple candidates receive identical assigned Lung Allocation Scores pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent approval of that Lung Allocation Score by the Lung Review Board was entered in UNetSM (For example, if Candidate X and Candidate Y have identical Lung Allocation Scores assigned to them by the Lung Review Board and identical priority for a lung offer, and the approval for Candidate X's score was entered in UNetSM on June 1, 2005, and the approval for Candidate Y's score was entered in UNetSM on July 1, 2005, then Candidate X would receive higher priority for the lung offer because his most recent Lung Allocation Score was approved and entered in UNetSM first.)

Candidates that receive a Lung Allocation Score of zero due to missing or expired candidate variables as described in Policy 3.7.6.3 will be screened from the lung match following notification of the listing center, and will not receive isolated lung offers. Upon the entry or update of previously missing or expired candidate variables as described in Policy 3.7.6.3, those candidates will appear on the lung match.

Candidates awaiting a lung transplant on the Waiting List at inactive status will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

NOTE: Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6) (BOLDED and as of the June 24, 2005 Board of Directors Meeting) shall be approved and implemented pending distribution of appropriate notice and programming on UNetSM, if and as applicable.

3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age.

Candidates listed as a Priority 1 or Priority 2 will accrue waiting time within each priority. Priority 1 and Priority 2 candidates will receive a preference over other candidates within a match run classification who have accumulated less waiting time. For Priority 1 candidates, UNetSM will only consider the most recent time spent as Priority 1, i.e., UNetSM will not tally the time waiting during multiple Priority 1 periods.

For Priority 2 candidates, and if there is ever a tie among Priority 1 candidates, UNetSM will use total waiting time. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

3.7.10 Sequence of Adult Heart Allocation. Donor hearts recovered from donors age 18 and older shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

Local

1. Status 1A candidates
2. Status 1B candidates

Zone A

3. Status 1A candidates
4. Status 1B candidates

Local

5. Status 2 candidate s

Zone B

6. Status 1A candidates
7. Status 1B candidates

Zone A

8. Status 2 candidates

Zone B

9. Status 2 candidates

Zone C

10. Status 1A candidates
11. Status 1B candidates
12. Status 2 candidates

Zone D

13. Status 1A candidates
14. Status 1B candidates
15. Status 2 candidates

Zone E

16. Status 1A candidates
17. Status 1B candidates
18. Status 2 candidates

3.7.10.1 Sequence of Pediatric Heart Allocation. Hearts recovered from pediatric donors shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

1. Common OPO and Zone A Status 1A ABO Primary Ped Candidates for Pediatric Donor
2. Common OPO and Zone A Status 1A ABO Secondary Ped

- Candidates for Pediatric Donor
3. Common OPO Status 1A ABO Primary Candidates
 4. Common OPO Status 1A ABO Secondary Candidates
 5. Common OPO and Zone A Status 1B ABO Primary Ped Candidates for Pediatric Donor
 6. Common OPO and Zone A Status 1B ABO Secondary Ped Candidates for Pediatric Donor
 7. Common OPO Status 1B ABO Primary Candidates
 8. Common OPO Status 1B ABO Secondary Candidates
 9. Zone A Status 1A ABO Primary Candidates
 10. Zone A Status 1A ABO Secondary Candidates
 11. Zone A Status 1B ABO Primary Candidates
 12. Zone A Status 1B ABO Secondary Candidates
 13. Common OPO Status 2 ABO Primary Ped Candidates for Pediatric Donor
 14. Common OPO Status 2 ABO Secondary Ped Candidates for Pediatric Donor
 15. Common OPO Status 2 ABO Primary Candidates
 16. Common OPO Status 2 ABO Secondary Candidates
 17. Zone B Status 1A ABO Primary Ped Candidates for Pediatric Donor
 18. Zone B Status 1A ABO Secondary Ped Candidates for Pediatric Donor
 19. Zone B Status 1A ABO Primary Candidates
 20. Zone B Status 1A ABO Secondary Candidates
 21. Zone B Status 1B ABO Primary Ped Candidates for Pediatric Donor
 22. Zone B Status 1B ABO Secondary Ped Candidates for Pediatric Donor
 23. Zone B Status 1B ABO Primary Candidates
 24. Zone B Status 1B ABO Secondary Candidates
 25. Zone A Status 2 ABO Primary Ped Candidates for Pediatric Donor
 26. Zone A Status 2 ABO Secondary Ped Candidates for Pediatric Donor
 27. Zone A Status 2 ABO Primary Candidates
 28. Zone A Status 2 ABO Secondary Candidates
 29. Zone B Status 2 ABO Primary Ped Candidates for Pediatric Donor
 30. Zone B Status 2 ABO Secondary Ped Candidates for Pediatric Donor
 31. Zone B Status 2 ABO Primary Candidates
 32. Zone B Status 2 ABO Secondary Candidates
 33. Zone C Status 1A ABO Primary Ped Candidates for Pediatric Donor
 34. Zone C Status 1A ABO Secondary Ped Candidates for Pediatric Donor
 35. Zone C Status 1A ABO Primary Candidates
 36. Zone C Status 1A ABO Secondary Candidates
 37. Zone C Status 1B ABO Primary Ped Candidates for Pediatric Donor
 38. Zone C Status 1B ABO Secondary Ped Candidates for Pediatric Donor
 39. Zone C Status 1B ABO Primary Candidates
 40. Zone C Status 1B ABO Secondary Candidates
 41. Zone C Status 2 ABO Primary Ped Candidates for Pediatric Donor
 42. Zone C Status 2 ABO Secondary Ped Candidates for Pediatric Donor
 43. Zone C Status 2 ABO Primary Candidates
 44. Zone C Status 2 ABO Secondary Candidates
 45. Zone D Status 1A ABO Primary Ped Candidates for Pediatric Donor
 46. Zone D Status 1A ABO Secondary Ped Candidates for Pediatric Donor
 47. Zone D Status 1A ABO Primary Candidates
 48. Zone D Status 1A ABO Secondary Candidates
 49. Zone D Status 1B ABO Primary Ped Candidates for Pediatric Donor
 50. Zone D Status 1B ABO Secondary Ped Candidates for Pediatric Donor

51. Zone D Status 1B ABO Primary Candidates
52. Zone D Status 1B ABO Secondary Candidates
53. Zone D Status 2 ABO Primary Ped Candidates for Pediatric Donor
54. Zone D Status 2 ABO Secondary Ped Candidates for Pediatric Donor
55. Zone D Status 2 ABO Primary Candidates
56. Zone D Status 2 ABO Secondary Candidates
57. Zone E Status 1A ABO Primary Ped Candidates for Pediatric Donor
58. Zone E Status 1A ABO Secondary Ped Candidates for Pediatric Donor
59. Zone E Status 1A ABO Primary Candidates
60. Zone E Status 1A ABO Secondary Candidates
61. Zone E Status 1B ABO Primary Ped Candidates for Pediatric Donor
62. Zone E Status 1B ABO Secondary Ped Candidates for Pediatric Donor
63. Zone E Status 1B ABO Primary Candidates
64. Zone E Status 1B ABO Secondary Candidates
65. Zone E Status 2 ABO Primary Ped Candidates for Pediatric Donor
66. Zone E Status 2 ABO Secondary Ped Candidates for Pediatric Donor
67. Zone E Status 2 ABO Primary Candidates
68. Zone E Status 2 ABO Secondary Candidates
69. Common OPO and Zone A Status 1A ABO Incompatible Ped Candidates for Pediatric Donor
70. Common OPO and Zone A Status 1B ABO Incompatible Ped Candidates for Pediatric Donor
71. Common OPO Status 2 ABO Incompatible Candidates
72. Zone B Status 1A ABO Incompatible Candidates
73. Zone B Status 1B ABO Incompatible Candidates
74. Zone C Status 1A ABO Incompatible Candidates
75. Zone C Status 1B ABO Incompatible Candidates
76. Zone D Status 1A ABO Incompatible Candidates
77. Zone D Status 1B ABO Incompatible Candidates
78. Zone E Status 1A ABO Incompatible Candidates
79. Zone E Status 1B ABO Incompatible Candidates
80. Common OPO and Zone A ABO Primary In Utero Candidates
81. Common OPO and Zone A ABO Secondary In Utero Candidates
82. Common OPO and Zone A ABO Incompatible In Utero Candidates
83. Zone B ABO Primary In Utero Candidates
84. Zone B ABO Secondary In Utero Candidates
85. Zone B ABO Incompatible In Utero Candidates
86. Zone C ABO Primary In Utero Candidates
87. Zone C ABO Secondary In Utero Candidates
88. Zone C ABO Incompatible In Utero Candidates
89. Zone D ABO Primary In Utero Candidates
90. Zone D ABO Secondary In Utero Candidates
91. Zone D ABO Incompatible In Utero Candidates
92. Zone E ABO Primary In Utero Candidates
93. Zone E ABO Secondary In Utero Candidates
94. Zone E ABO Incompatible In Utero Candidates

3.7.11 Sequence of Adult Donor Lung Allocation. Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation. If one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood

type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for adult donor lungs is as follows:

1. Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
2. Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
3. Local ABO identical Priority 1 candidates 0 – 11 years old according to length of waiting time;
4. Local ABO compatible Priority 1 candidates 0 – 11 years old according to length of waiting time;
5. Local ABO identical Priority 2 candidates 0 – 11 years old according to length of waiting time;
6. Local ABO compatible Priority 2 candidates 0 – 11 years old according to length of waiting time;
7. ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
8. ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
9. ABO identical Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
10. ABO compatible Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
11. ABO identical Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
12. ABO compatible Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
13. ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
14. ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
15. ABO identical Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
16. ABO compatible Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
17. ABO identical Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
18. ABO compatible Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
19. ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
20. ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
21. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;
22. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;
23. ABO identical Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;
24. ABO compatible Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;
25. ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
26. ABO compatible candidates age 12 and older in Zone D according to Lung

- Allocation Score in descending order;
27. ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;
 28. ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;
 29. ABO identical Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;
 30. ABO compatible Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;
 31. ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
 32. ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
 33. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time;
 34. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time;
 35. ABO identical Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time; and
 36. ABO compatible Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time.

3.7.11.1 **Sequence of Pediatric Donor Lung Allocation.** Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. Candidates will be grouped so that those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to **combined** local, Zone A and Zone B candidates by priority and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.
- Offers for 12-17 year-olds will first be made to **combined** local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are

completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.

- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0-11 years old is as follows:

1. Combined local, Zone A and Zone B ABO identical Priority 1 candidates 0-11 years old according to length of waiting time;
2. Combined local, Zone A and Zone B ABO compatible Priority 1 candidates 0-11 years old according to length of waiting time;
3. Combined local, Zone A and Zone B ABO identical Priority 2 candidates 0-11 years old according to length of waiting time;
4. Combined local, Zone A and Zone B ABO compatible Priority 2 candidates 0-11 years old according to length of waiting time;
5. Combined local and Zone A ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
6. Combined Local and Zone A ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
7. Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
8. Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
9. ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
10. ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
11. ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
12. ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
13. ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
14. ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
15. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
16. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
17. ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;
18. ABO compatible Priority 2 candidates 0-11 years old in Zone C according to length of waiting time;
19. ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
20. ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
21. ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
22. ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

23. ABO identical Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
24. ABO compatible Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
25. ABO identical Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
26. ABO compatible Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
27. ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
28. ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
29. ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
30. ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
31. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
32. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
33. ABO identical Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
34. ABO compatible Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
35. ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
36. ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
37. ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
38. ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidates age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

1. Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
2. Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
3. Local ABO identical Status 1 candidates 0 – 11 years old according to length of time waiting;
4. Local ABO compatible Status 1 candidates 0 – 11 years old according to length of time waiting;
5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of time waiting;
6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of time waiting;
7. Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
8. Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
9. ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
10. ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
11. ABO identical Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
12. ABO compatible Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
13. ABO identical Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
14. ABO compatible Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
15. ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
16. ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
17. ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
18. ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
19. ABO identical Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
20. ABO compatible Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
21. ABO identical Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;

22. ABO compatible Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
23. ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
24. ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
25. ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
26. ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
27. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
28. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
29. ABO identical Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
30. ABO compatible Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
31. ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
32. ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
33. ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
34. ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
35. ABO identical Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
36. ABO compatible Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
37. ABO identical Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
38. ABO compatible Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
39. ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
40. ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
41. ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
42. ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
43. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
44. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
45. ABO identical Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
46. ABO compatible Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
47. ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
48. ABO compatible candidates 18 years old and older in Zone E.

3.7.12 Minimum Information for Thoracic Organ Offers.

- 3.7.12.1 Essential Information.** The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

- (i) The cause of brain death;
- (ii) The details of any documented cardiac arrest or hypotensive episodes;
- (iii) Vital signs including blood pressure, heart rate and temperature;
- (iv) Cardiopulmonary, social, and drug activity histories;
- (v) Serologies as indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1);
- (vi) Accurate height, weight, age and sex;
- (vii) ABO type;
- (viii) ABO subtype when used for allocation;
- (ix) Interpreted electrocardiogram and chest radiograph;
- (x) History of treatment in hospital including vasopressors and hydration;
- (xi) Arterial blood gas results and ventilator settings;
- (xii) Echocardiogram, if the donor hospital has the facilities; and
- (xiii) Human leukocyte antigen (HLA) type if requested by the transplant center.

If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ's final acceptance: HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR, and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

3.7.12.2 Desirable Information for Heart Offers. With each heart offer, the donor center is encouraged to provide the recipient center with the following information:

- (i) Coronary angiography for male donors over the age of 40 and female donors over the age of 45;
- (ii) CVP or Swan Ganz instrumentation;
- (iii) Cardiology consult; and
- (iv) Cardiac enzymes including CPK isoenzymes.

With each heart offer, it is reasonable for the transplanting center to request a heart catheterization of the donor where the donor history reveals one or more of the following:

- (a) The donor is a male over the age of 40 or a female over the age of 45;
- (b) Segmental wall motion abnormality;
- (c) Troponin elevation;
- (d) History of chest pain;
- (e) Abnormal EKG consistent with ischemia or myocardial infarction; or
- (f) Two or more of the following:
 - i. History of hypertension
 - ii. History of significant smoking
 - iii. Intra-cerebral bleed
 - iv. Strong family history of coronary artery disease
 - v. History of Hyperlipidemia

- vi. History of diabetes
- vii. History of cocaine or amphetamine use

3.7.12.3 Essential Information for Lung Offers. In addition to the essential information specified above for a thoracic organ offer, the Host OPO shall provide the following specific information with each lung offer:

- (i) Arterial blood gases on 5 cm/H₂O/PEEP including PO₂/FiO₂ ratio and preferably 100% FiO₂ within 2 hours prior to the offer;
- (ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation. The Host OPO must document if it is unable to provide bronchoscopy results. Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.2;
- (iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;
- (iv) Sputum gram stain with a description of the sputum character; and
- (v) Smoking history.

3.7.12.4 Desirable Information for Lung Offers. With each lung offer, the Host OPO is encouraged to provide the transplant center with the following information:

- (i) Mycology smear;
- (ii) Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested; and
- (iii) Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

3.7.13 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased. If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

3.7.14 Local Conflicts Involving Thoracic Organ Allocation. Regarding allocation of hearts, lungs and heart-lung combinations, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Thoracic Organ Transplantation Committee and the Board of Directors.

3.7.15 Allocation of Domino Donor Hearts. A domino heart transplant occurs when the native heart of a combined heart-lung transplant recipient is procured and transplanted into a candidate who requires an isolated heart transplant. First consideration for donor hearts procured for this purpose will be given to the candidates of the participating transplant program from which the native heart was procured. If the program elects not to use the heart, then the heart will be allocated according to Policy 3.7, or an approved

variance to this policy. For the purpose of Policy 3.7.16, the Local Unit of allocation for the domino heart shall be defined as the CMS-designated service area of the OPO where the domino heart is procured.

- 3.7.16 Crossmatching for Thoracic Organs.** The transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.