

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.

- (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 ≥ 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 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 3.7.3. Candidates listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNetSM 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 UNetSM 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 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 ≥ 0.50 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)
<u>Bilirubin (current bilirubin – all gGroups; 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 ≥ 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, lymphangioliomyomatosis, 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 $[(\text{current PCO}_2 - \text{lowest PCO}_2) / \text{lowest PCO}_2]$.

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

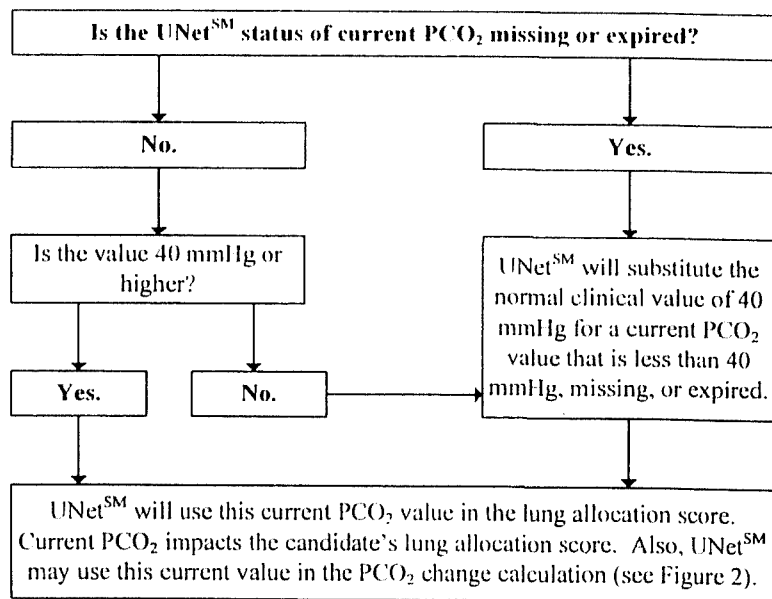


Figure 2
PCO₂ Threshold Change Calculation

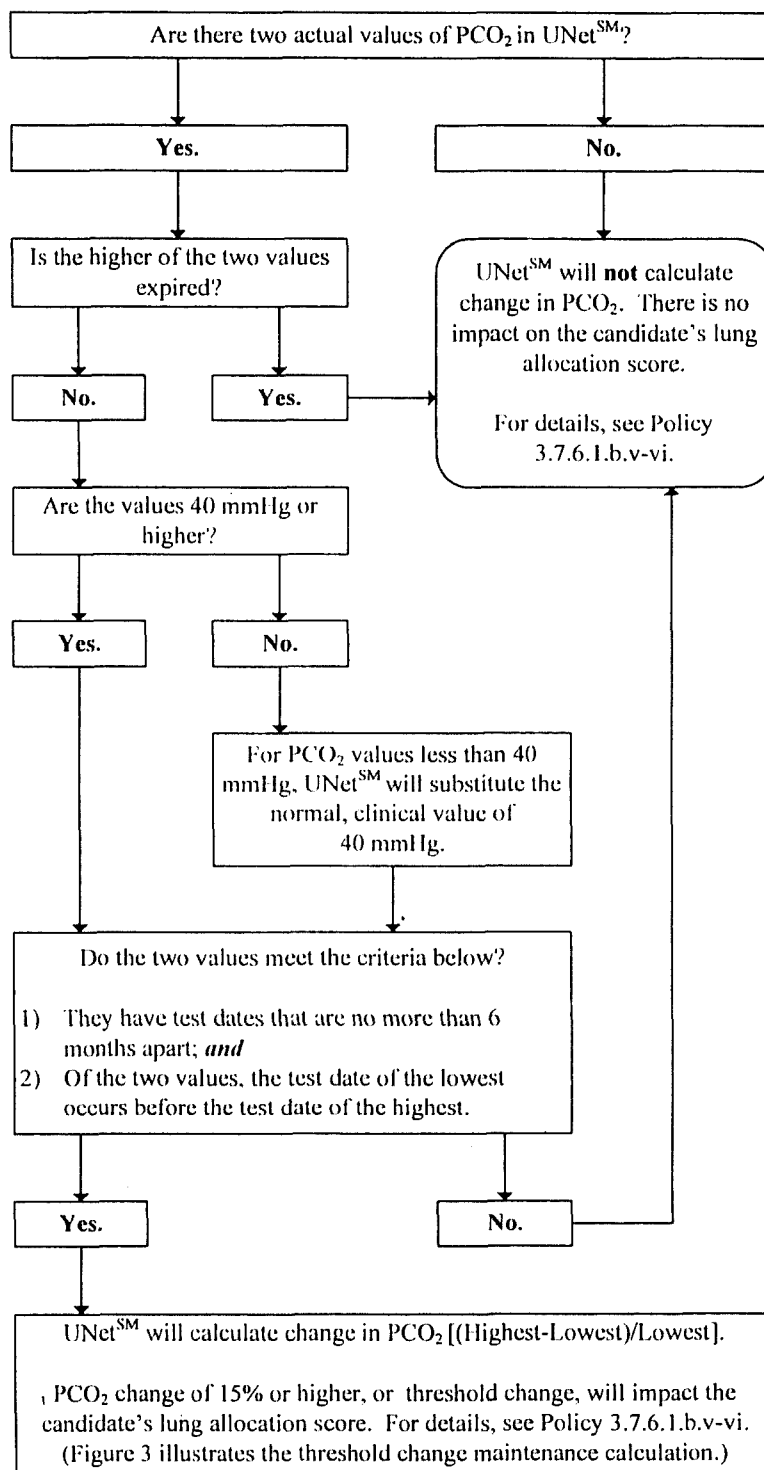
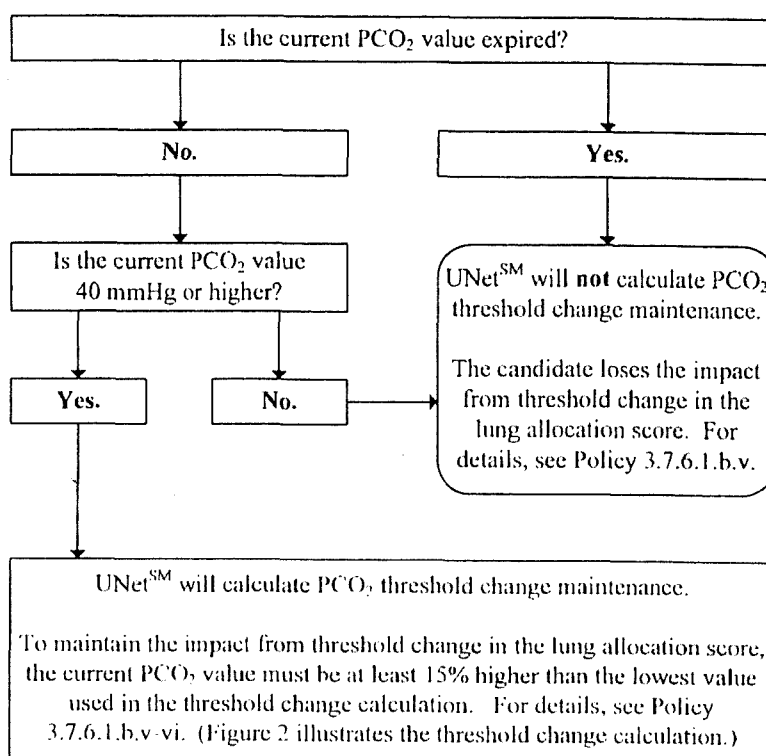


Figure 3
PCO₂ Threshold Change Maintenance Calculation



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.