OPTN/UNOS Thoracic Organ Transplantation Committee
Report to the Board of Directors
November 12-13, 2012
St. Louis, Missouri

Summary

I. Action Item For Board Consideration

- The Board is asked to approve the *Proposal to Revise the Lung Allocation Score (LAS) System*, which includes changes to Policies 3.7.6 (Lung Allocation System) and 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). The proposed changes include: 1) modifications to the covariates in the waiting list urgency and post-transplant survival models, coefficients of the covariates, and baseline waiting list and post-transplant survival rates used in the LAS calculation; and 2) revisions to the LAS system to prioritize candidates using data derived from a candidate population transplanted due to their LASs, instead of their waiting time. (Item 1, page 3)

II. Other Significant Items

- The Committee voted to allow the provision of Policy 3.7.3, granting 30 days of status 1A time to outpatient candidates implanted with total artificial hearts, to expire on December 1, 2012. (Item 2, page 36)

- The Committee, along with the Liver and Intestinal Organ Transplantation Committee, sponsored a proposal to modify and streamline the Heart and Liver Regional Review Board Guidelines, as well as the Lung Review Board Guidelines. On August 28, 2012, the Executive Committee approved the changes, which also include modifications to Policies 3.7.3 (Adult Candidate Status), 3.7.4 (Pediatric Candidate Status), 3.7.6.2 (Candidates Age 0-11), and 3.7.6.4 (Lung Candidates with Exceptional Cases). (Item 3, page 38)

- The Committee, along with the Membership and Professional Standards Committee (MPSC), distributed the *Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation* for public comment on September 21, 2012. The proposed change removes Appendix J (Membership and Personnel Requirements for Combined Heart and Lung Program) from the OPTN bylaws. There are no such bylaws for designating other single combined organ transplant programs. (Item 4, page 38)

- The Committee plans to distribute the *Proposal to Change Pediatric Heart Allocation Policy* for public comment in March 2012. The proposal includes: 1) changes to the pediatric heart medical urgency criteria for Status 1A and Status 1B; 2) lowering of isohemagglutinin titer level for certain candidates willing to accept ABO-incompatible heart transplants; 3) elevating the allocation priority of candidates willing to receive ABO-incompatible heart

offers; and, 4) disallowing registration of candidates *in utero* on the waiting list. (Item 5, page 39)

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The Thoracic Organ Transplantation Committee (the Committee) met by telephone and Internet on July 16, 2012, and in-person in Chicago, Illinois on September 5, 2012. The following is a summary of these meetings.

1. Proposal to Revise the Lung Allocation Score (LAS) System

The Committee reviewed comments submitted by the public, transplant societies, UNOS Regions, and OPTN/UNOS committees in response to this policy proposal. The public, transplant societies, and the Regions voted in favor of the policy revisions. One OPTN/UNOS committee voted in favor of the proposal and the remaining committees did not comment. The Committee voted in favor of submitting the following resolution to the Board of Directors for its review in November 2012: 28-supported; 0-opposed; and, 0-abstained. (**Exhibit A**).

****RESOLVED, that Policies 3.7.6 (Lung Allocation System) and 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) shall be modified as set forth below, effective pending programming and notice to the OPTN membership:**

Policy Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~) Policy language that is double-underlined or double struck through has been modified since the public comment proposal.

3.7.6 Lung Allocation Candidates waiting for lung transplants receive priority for deceased donor lung offers based on Lung Allocation Score (LAS) if they are at least 12 years of age~~, or medical urgency priority if they are less than 12 years of age~~. Candidates less than 12 years of age receive deceased donor lung offers based on or medical urgency priority.

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

3.7.6.1 Lung Allocation Score (LAS) System for Candidates at Least 12 Years of Age

Candidates who are at least 12 years of age receive offers for deceased donor lungs based on LAS, as well as geography and blood type. Candidates with higher LASs receive higher waiting list priority.

~~**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.~~

3.7.6.1.1 The LAS Calculation

~~a) The LAS Calculation~~

The LAS calculation uses *all of* the following ~~measures~~:

- Waitlist U~~u~~rgency M~~m~~easure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list~~waitlist;~~
- Post-transplant S~~s~~urvival M~~m~~easure, which is the expected number of days a candidate will live during the first year post-transplant~~; and,~~
- Transplant B~~b~~enefit M~~m~~easure, which is the difference between the Post-transplant S~~s~~urvival M~~m~~easure and the Waitlist U~~u~~rgency M~~m~~easure~~.~~

~~The LAS calculation is the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure. A Raw Allocation Score ranges in days from negative 730 to positive 365. To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of 0 to 100.~~

The LAS is determined by normalizing the Raw Allocation Score to a continuous scale of 0 to 100. The Raw Allocation Score is the difference between the Transplant Benefit Measure and the Waitlist Urgency Measure.

The equation for the LAS calculation is:

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

~~where~~

$$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$$

$$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$$

$$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$$

$$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$$

~~The LAS calculation includes the following components:~~

- ~~PTAUC: the area under the post-transplant survival probability curve during the first post-transplant year~~
- ~~$S_{TX,0}(t)$: the baseline post-transplant survival probability at time t (see Table 5)~~
- ~~$S_{TX}(t)$: the expected post-transplant survival probability at time t for an individual candidate~~
- ~~Y_j: the value of the jth characteristic for an individual candidate (e.g., candidate is on continuous mechanical ventilation)~~
- ~~α_j:the coefficient for characteristic j from the post-transplant model (see Table 3) (e.g., $\alpha_{ventilation}$=0.61)~~
- ~~WLAUC: the area under the waiting list survival probability curve during the next year~~
- ~~$S_{WL,0}(t)$: the baseline waiting list survival probability at time t (see Table 4)~~
- ~~$S_{WL}(t)$: the expected waiting list survival probability at time t for an individual candidate~~
- ~~X_j: the value of the jth characteristic for an individual candidate (e.g., candidate is diabetic)~~
- ~~β_j: the coefficient for characteristic j from the waiting list model (see Table 1) (e.g., $\beta_{diabetes}$=0.47)~~

Where…	**Includes…**
$$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$$	PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.
$$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_j = the value of the jth characteristic for an individual candidate α_j = the coefficient for characteristic j from the post-transplant model, according to Table 2.
$$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$$	WLAUC = the area under the waiting list survival probability curve during the next year.
$$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$$	$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to Table 3. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at

Where…	Includes…
	time t, according to Table 4. $S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate X_i = the value of the ith characteristic for an individual candidate. β_i: the coefficient for characteristic i from the waiting list model, according to Table 1.

~~Tables 1 and 2 list the covariates and their coefficients in the waiting list and post-transplant survival models.~~

Table 1

Factors Used in the Waiting List Mortality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (~~per 10~~ year~~s~~)	0.0083990318885565*age
2. Bilirubin (per ~~1~~ mg/dL)	0.0431682188302477*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL (see Policy 3.7.6.1.4) 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Group B (see Policy 3.7.6.1.4) 0 for Groups A, C, and D (see Policy 3.7.6.1.2)
4. Body mass index (BMI; ~~per 1~~ kg/m^2)	0.1261444133358100*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2

For this covariate:	**The following coefficient is used in the LAS calculation:**
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 L/min/m^2 0 if the cardiac index is at least 2 L/min/m^2
6. Central venous pressure (CVP; ~~per 1~~ mm Hg) at rest, prior to any exercise	0.0173841981251578*(CVP – 7) for CVP greater than 7 mm Hg (Group B only – see Policy 3.7.6.1.2.b) 0 if less than or equal to 7 mm Hg for Group B (see Policy 3.7.6.1.2.b) 0 for candidates in Groups A, C, and D (see Policy 3.7.6.1.2)
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum~~)~~, ~~per~~ mg/dL)	0.5034346761960600*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A (see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	1.5774243292137200

For this covariate:	The following coefficient is used in the LAS calculation:
Diagnosis Group C (see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.c for the diseases included in this group)	1.2313926484343600
Diagnosis Group D (see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d for the diseases included in this group)	0.6259577164157700
11. Detailed diagnosis: Bronchiectasis (Group A – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a)	0.6680518055684700
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.b)	-0.6278657824830000
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a)	-0.3162937838984600
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d)	0.4453284411081100
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d)	-0.2091170018125500
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d)	-0.4577749354638600
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a)	0.9330846239906700

For this covariate:	The following coefficient is used in the LAS calculation:
12. Forced vital capacity (FVC) ~~(per 10%)~~	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Group D (see Policy 3.7.6.1.2.d) 0 if FVC is greater than or equal to 80% for Group D (see Policy 3.7.6.1.2.d) 0 for candidates in Groups A, B, and C (see Policy 3.7.6.1.2)
13. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
14. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (~~per~~ L/min)	0.0213187586203456*O_2 for Group B (see Policy 3.7.6.1.2.b) 0.1188479817592500 for Groups A, C, and D (see Policy 3.7.6.1.2)
15. PCO_2 (~~per 10~~ mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg (see Policy 3.7.6.1.3)
16. PCO_2 increase of at least 15% (see Policy ~~3.7.6.1.b~~ 3.7.6.1.3)	0.2331149280428300 if PCO_2 increase is at least 15% (see Policy 3.7.6.1.3) 0 if PCO_2 increase is less than 15% (see Policy 3.7.6.1.3)

For this covariate:	**The following coefficient is used in the LAS calculation:**
17. Pulmonary artery (PA) systolic pressure (~~per~~ 10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Group A if the PA systolic pressure is greater than 40 mm Hg (see Policy 3.7.6.1.2.a) 0 for Group A if the PA systolic pressure is 40 mm Hg or less (see Policy 3.7.6.1.2.a) 0.0462410402627318*PA systolic/10 for Groups B, C, and D (see Policy 3.7.6.1.2)
18. Six minute walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.0844896372724000*Six-minute walk distance/100 ~~0.00 if six-minute distance walked is more than 1200 feet~~

~~**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[1] – see 3.7.6.1.a)~~
~~3. O_2 required at rest (Groups A, C, and D[1] – 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)~~
~~Bilirubin (current bilirubin – all gGroups; change in bilirubin –~~

~~12. Group B; see 3.7.6.1.c)~~

Table 2

Factors Used in the Post-Transplant Survival Calculation: Covariates and their Coefficients

For this covariate:	**The following coefficient is used in the LAS calculation:**
1. Age ~~per year~~ (years)	0.0246579831271869*(age – 45) if greater than 45 years of age 0 if 45 years of age or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age
3. Creatinine ~~(~~increase of at least 150%~~)~~	0.7708616024698100 if increase in creatinine is at least 150%, and when the higher value determining this increase is at least 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine less than 150% or creatinine decreases (see Policy 3.7.6.1.5)
4. Cardiac index (L/min/m^2) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed

For this covariate:	The following coefficient is used in the LAS calculation:
6. Diagnosis Group A (see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	0.6115547319209300
Diagnosis Group C (see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.c for the diseases included in this group)	0.3627014422464200
Diagnosis Group D (see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d for the diseases included in this group)	0.4641392063023200
7. Detailed diagnosis: Bronchiectasis (Group A – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a)	0.1889100379099400
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.b)	0.9146727886744700
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a)	-1.5194416206749400
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d)	-1.2050508750702600
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d)	-0.0723596761367600
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.d)	-0.0437880049066331

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy ~~3.7.6.1.b~~ 3.7.6.1.2.a)	-0.1389363636019300
8. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0747978926517300*O_2 for Group A (see Policy 3.7.6.1.2.a) 0.0164276945879309 for Groups B, C, and D (see Policy 3.7.6.1.2)
9. Functional Status	-0.1900086366785100 if no assistance needed with activities for daily living 0 if some or total assistance needed with activities for daily living
10. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-6mw) 0 if six-minute-distance-walked is ~~more than~~ at least 1200 feet

~~**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.~~

Tables 3 and 4 provide the baseline waiting list and post-transplant survival probabilities, which are used in the LAS calculation.

Table 3: Baseline Waiting List Survival ($S_{WL}(t)$) Probability

Time (days) : t	$S_{WL}(t)$	Time (days) : t	$S_{WL}(t)$	Time (days) : t	$S_{WL}(t)$	Time (days) : t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
0	1.000000	49	0.996644	98	0.993160	147	0.990540	196	0.987299
1	0.999991	50	0.996543	99	0.993098	148	0.990540	197	0.987263
2	0.999925	51	0.996518	100	0.993061	149	0.990540	198	0.987155
3	0.999867	52	0.996397	101	0.993005	150	0.990540	199	0.987122
4	0.999746	53	0.996397	102	0.993005	151	0.990540	200	0.986530
5	0.999598	54	0.996363	103	0.992938	152	0.990384	201	0.986530
6	0.999499	55	0.996305	104	0.992938	153	0.990333	202	0.986480
7	0.999371	56	0.996191	105	0.992883	154	0.990333	203	0.985963
8	0.999305	57	0.996119	106	0.992883	155	0.990333	204	0.985926
9	0.999218	58	0.995942	107	0.992851	156	0.990245	205	0.985926
10	0.999085	59	0.995942	108	0.992762	157	0.990245	206	0.985820
11	0.998990	60	0.995909	109	0.992724	158	0.990245	207	0.985820
12	0.998887	61	0.995909	110	0.992643	159	0.990145	208	0.985742
13	0.998816	62	0.995873	111	0.992643	160	0.989689	209	0.985742
14	0.998730	63	0.995846	112	0.992562	161	0.989689	210	0.985742
15	0.998660	64	0.995846	113	0.992089	162	0.989652	211	0.985708
16	0.998588	65	0.995614	114	0.992064	163	0.989575	212	0.985708
17	0.998455	66	0.995553	115	0.992040	164	0.989575	213	0.985541
18	0.998362	67	0.995553	116	0.991997	165	0.988903	214	0.985541
19	0.998259	68	0.995553	117	0.991966	166	0.988873	215	0.985541
20	0.998220	69	0.995500	118	0.991940	167	0.988873	216	0.985450
21	0.998068	70	0.995479	119	0.991940	168	0.988784	217	0.985450
22	0.998036	71	0.995349	120	0.991940	169	0.988722	218	0.985450
23	0.997972	72	0.995293	121	0.991514	170	0.988695	219	0.985330
24	0.997868	73	0.995136	122	0.991514	171	0.988695	220	0.985265
25	0.997770	74	0.994965	123	0.991514	172	0.988695	221	0.985265
26	0.997742	75	0.994821	124	0.991514	173	0.988655	222	0.985265

Time (days) : t	$S_{WL}(t)$	Time (days) : t	$S_{WL}(t)$	Time (days) : t	$S_{WL}(t)$	Time (days) : t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
27	0.997667	**76**	0.994774	**125**	0.991488	**174**	0.988655	**223**	0.985265
28	0.997626	**77**	0.994702	**126**	0.991462	**175**	0.988655	**224**	0.985265
29	0.997540	**78**	0.994702	**127**	0.991393	**176**	0.988625	**225**	0.984621
30	0.997473	**79**	0.994634	**128**	0.991307	**177**	0.988548	**226**	0.984549
31	0.997391	**80**	0.994565	**129**	0.991307	**178**	0.988548	**227**	0.984549
32	0.997327	**81**	0.994547	**130**	0.991270	**179**	0.988548	**228**	0.984549
33	0.997297	**82**	0.994465	**131**	0.991236	**180**	0.988062	**229**	0.984549
34	0.997274	**83**	0.994465	**132**	0.991236	**181**	0.988062	**230**	0.984489
35	0.997242	**84**	0.994297	**133**	0.991053	**182**	0.988062	**231**	0.984489
36	0.997242	**85**	0.994297	**134**	0.991012	**183**	0.988021	**232**	0.984396
37	0.997181	**86**	0.994297	**135**	0.991012	**184**	0.987934	**233**	0.984324
38	0.997137	**87**	0.994297	**136**	0.990978	**185**	0.987885	**234**	0.984280
39	0.997121	**88**	0.994181	**137**	0.990978	**186**	0.987885	**235**	0.984079
40	0.997121	**89**	0.994077	**138**	0.990978	**187**	0.987885	**236**	0.984079
41	0.997019	**90**	0.994035	**139**	0.990936	**188**	0.987885	**237**	0.984015
42	0.996946	**91**	0.994008	**140**	0.990901	**189**	0.987856	**238**	0.984015
43	0.996916	**92**	0.993866	**141**	0.990901	**190**	0.987856	**239**	0.984015
44	0.996849	**93**	0.993831	**142**	0.990811	**191**	0.987856	**240**	0.984015
45	0.996849	**94**	0.993807	**143**	0.990739	**192**	0.987856	**241**	0.983835
46	0.996820	**95**	0.993715	**144**	0.990595	**193**	0.987856	**242**	0.983835
47	0.996780	96	0.993308	145	0.990595	194	0.987608	243	0.983792
48	0.996731	97	0.993220	146	0.990540	195	0.987359	244	0.983753

Table 3: Baseline Waiting List Survival ($S_{WL}(t)$) Probability (Continued)

Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
245	0.983753	**269**	0.982960	**293**	0.981827	**317**	0.980218	**341**	0.978597
246	0.983753	**270**	0.982960	**294**	0.981827	**318**	0.980129	**342**	0.978597
247	0.983697	**271**	0.982797	**295**	0.981573	**319**	0.980129	**343**	0.978301
248	0.983636	**272**	0.982797	**296**	0.981319	**320**	0.980016	**344**	0.978250
249	0.983636	**273**	0.982797	**297**	0.980775	**321**	0.980016	**345**	0.978250
250	0.983636	**274**	0.982797	**298**	0.980775	**322**	0.980016	**346**	0.978250
251	0.983636	**275**	0.982700	**299**	0.980519	**323**	0.979773	**347**	0.978117
252	0.983243	**276**	0.982603	**300**	0.980397	**324**	0.979773	**348**	0.978037
253	0.983243	**277**	0.982603	**301**	0.980397	**325**	0.979671	**349**	0.978037
254	0.983243	**278**	0.982511	**302**	0.980397	**326**	0.979671	**350**	0.978037
255	0.983097	**279**	0.982457	**303**	0.980397	**327**	0.979164	**351**	0.978037
256	0.983097	**280**	0.982457	**304**	0.980397	**328**	0.979164	**352**	0.977937
257	0.983097	**281**	0.982457	**305**	0.980397	**329**	0.979164	**353**	0.977937
258	0.983097	**282**	0.982413	**306**	0.980397	**330**	0.979164	**354**	0.977937
259	0.983097	**283**	0.982323	**307**	0.980339	**331**	0.979100	**355**	0.977855
260	0.983097	**284**	0.982323	**308**	0.980339	**332**	0.979100	**356**	0.977855
261	0.983097	**285**	0.982323	**309**	0.980339	**333**	0.978935	**357**	0.977855
262	0.983052	**286**	0.982323	**310**	0.980339	**334**	0.978935	**358**	0.977710
263	0.983052	**287**	0.982323	**311**	0.980339	**335**	0.978817	**359**	0.977710
264	0.983052	**288**	0.982323	**312**	0.980339	**336**	0.978817	**360**	0.976881
265	0.983052	**289**	0.982323	**313**	0.980339	**337**	0.978817	**361**	0.976881
266	0.983052	**290**	0.982323	**314**	0.980339	**338**	0.978817	**362**	0.976881
267	0.983052	**291**	0.981916	**315**	0.980218	**339**	0.978817	**363**	0.976709
268	0.982960	**292**	0.981878	**316**	0.980218	**340**	0.978817	**364**	0.976709

Table 4: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
0	1.000000	48	0.981882	97	0.972415	146	0.965165	195	0.958585
0	0.998946	49	0.981394	98	0.972415	147	0.965018	196	0.958585
1	0.997558	50	0.981115	99	0.972128	148	0.965018	197	0.958511
2	0.996895	51	0.980836	100	0.971984	149	0.964724	198	0.958361
3	0.996364	52	0.980416	101	0.971769	150	0.964651	199	0.958062
4	0.995498	53	0.980207	102	0.971697	151	0.964504	200	0.958062
5	0.995165	54	0.980137	103	0.971553	152	0.964357	201	0.957987
6	0.994565	55	0.979926	104	0.971337	153	0.964063	202	0.957987
7	0.994164	56	0.979646	105	0.971265	154	0.963843	203	0.957913
8	0.993963	57	0.979436	106	0.971193	155	0.963696	204	0.957763
9	0.993360	58	0.979085	107	0.971121	156	0.963475	205	0.957613
10	0.993159	59	0.978874	108	0.971049	157	0.963328	206	0.957538
11	0.992487	60	0.978733	109	0.970977	158	0.963107	207	0.957388
12	0.992353	61	0.978452	110	0.970761	159	0.962738	208	0.957313
13	0.991949	62	0.978382	111	0.970689	160	0.962517	209	0.957238
14	0.991679	63	0.978170	112	0.970617	161	0.962443	210	0.957163
15	0.991207	64	0.978100	113	0.970545	162	0.962296	211	0.957163
16	0.990531	65	0.977959	114	0.970473	163	0.962074	212	0.956938
17	0.990260	66	0.977818	115	0.970329	164	0.961927	213	0.956863
18	0.989921	67	0.977818	116	0.969968	165	0.961705	214	0.956788
19	0.989582	68	0.977536	117	0.969824	166	0.961631	215	0.956713
20	0.989514	69	0.977254	118	0.969679	167	0.961557	216	0.956638
21	0.988902	70	0.977042	119	0.969607	168	0.961483	217	0.956488
22	0.988220	71	0.976971	120	0.969390	169	0.961483	218	0.956263
23	0.987810	72	0.976901	121	0.969101	170	0.961409	219	0.956263
24	0.987469	73	0.976759	122	0.968956	171	0.961113	220	0.956187

25	0.987263	**74**	0.976547	**123**	0.968667	**172**	0.961113	**221**	0.956112
26	0.987058	**75**	0.976476	**124**	0.968594	**173**	0.961039	**222**	0.956037
27	0.986578	**76**	0.976193	**125**	0.968377	**174**	0.960965	**223**	0.955887
28	0.986304	**77**	0.975909	**126**	0.968159	**175**	0.960891	**224**	0.955736
29	0.986030	**78**	0.975767	**127**	0.968086	**176**	0.960743	**225**	0.955736
30	0.985961	**79**	0.975625	**128**	0.967868	**177**	0.960595	**226**	0.955736
31	0.985755	**80**	0.975483	**129**	0.967796	**178**	0.960446	**227**	0.955661
32	0.985480	**81**	0.975483	**130**	0.967504	**179**	0.960446	**228**	0.955661
33	0.985136	**82**	0.975483	**131**	0.967359	**180**	0.960372	**229**	0.955510
34	0.984929	**83**	0.974985	**132**	0.967140	**181**	0.960298	**230**	0.955510
35	0.984515	**84**	0.974985	**133**	0.967140	**182**	0.960149	**231**	0.955209
36	0.984446	**85**	0.974700	**134**	0.966994	**183**	0.960075	**232**	0.955209
37	0.984170	**86**	0.974700	**135**	0.966702	**184**	0.959852	**233**	0.955134
38	0.983825	**87**	0.974415	**136**	0.966483	**185**	0.959778	**234**	0.954983
39	0.983479	**88**	0.973987	**137**	0.966483	**186**	0.959703	**235**	0.954832
40	0.983202	**89**	0.973845	**138**	0.966410	**187**	0.959629	**236**	0.954681
41	0.983063	**90**	0.973630	**139**	0.966263	**188**	0.959554	**237**	0.954530
42	0.982855	**91**	0.973416	**140**	0.966190	**189**	0.959480	**238**	0.954455
43	0.982716	**92**	0.973416	**141**	0.966190	**190**	0.959256	**239**	0.954228
44	0.982578	**93**	0.973202	**142**	0.965971	**191**	0.959107	**240**	0.954228
45	0.982300	**94**	0.973059	**143**	0.965751	**192**	0.959033	**241**	0.954077
46	0.982160	**95**	0.972916	**144**	0.965678	**193**	0.959033	**242**	0.954077
47	0.981952	**96**	0.972629	**145**	0.965311	**194**	0.958735	**243**	0.953925

Table 4: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability (Continued)

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
244	0.953850	269	0.951190	293	0.948589	317	0.946359	341	0.943729
245	0.953850	270	0.950961	294	0.948359	318	0.946359	342	0.943651
246	0.953774	271	0.950656	295	0.948282	319	0.946204	343	0.943573
247	0.953774	272	0.950579	296	0.948128	320	0.946204	344	0.943418
248	0.953698	273	0.950427	297	0.948052	321	0.946127	345	0.943341
249	0.953623	274	0.950274	298	0.947975	322	0.946050	346	0.943108
250	0.953395	275	0.950121	299	0.947821	323	0.946050	347	0.943030
251	0.953319	276	0.950121	300	0.947667	324	0.945896	348	0.943030
252	0.953016	277	0.949815	301	0.947667	325	0.945818	349	0.942952
253	0.953016	278	0.949662	302	0.947360	326	0.945587	350	0.942719
254	0.952712	279	0.949662	303	0.947360	327	0.945432	351	0.942719
255	0.952712	280	0.949585	304	0.947360	328	0.945432	352	0.942719
256	0.952712	281	0.949585	305	0.947360	329	0.945355	353	0.942641
257	0.952484	282	0.949432	306	0.947283	330	0.945278	354	0.942485
258	0.952408	283	0.949355	307	0.947283	331	0.945123	355	0.942485
259	0.952332	284	0.949279	308	0.947206	332	0.945123	356	0.942173
260	0.952256	285	0.949279	309	0.947129	333	0.944968	357	0.942017
261	0.952180	286	0.949202	310	0.946975	334	0.944891	358	0.941783
262	0.952104	287	0.949202	311	0.946821	335	0.944736	359	0.941705
263	0.951876	288	0.949126	312	0.946821	336	0.944581	360	0.941627
264	0.951800	289	0.949049	313	0.946821	337	0.944504	361	0.941549
265	0.951648	290	0.948896	314	0.946744	338	0.944194	362	0.941549
266	0.951648	291	0.948819	315	0.946590	339	0.944039	363	0.941315
267	0.951572	292	0.948819	316	0.946436	340	0.943961	364	0.941315
268	0.951495								

3.7.6.1.2 Lung Disease Diagnosis Group Classification in the Lung Allocation Score (LAS)

~~b) Lung Disease Diagnosis and its Group Classification~~

The LAS calculation ~~makes use of~~ includes four diagnosis groups: A, B, C, and D. The diagnoses that comprise each group are:

a. ~~(i)~~Group A
- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

b. ~~(ii)~~Group B
- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: Patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: Ventricular septal defect (VSD)
- Portopulmonary hypertension
- Primary pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

c. ~~(iii)~~Group C
- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

d. ~~(iv)~~Group D

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchoalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with one or more of the following disease entities:
    - Acute interstitial pneumonia
    - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
    - Desquamative interstitial pneumonia
    - Idiopathic pulmonary fibrosis
    - Nonspecific interstitial pneumonia
    - Lymphocytic interstitial pneumonia
    - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis (specify cause)
- Silicosis
- Sjogren's syndrome

- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

~~a. Lung Disease Diagnosis Group~~

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

~~(i) *Group A*~~

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

3.7.6.1.3 PCO_2 in the Lung Allocation Score (LAS)

~~a. PCO_2 in the Lung Allocation Score~~

~~[Except for the change in this policy's number – from 3.7.6.1.b to 3.7.6.1.c – there are no further changes to this policy.]~~

UNet^{SM} will use two measures of PCO_2 in a candidate's lung allocation score calculation: current PCO_2, and change in PCO_2. There are two types of PCO_2 change calculations: "threshold change" and "threshold change maintenance." The following explanations (a-f)~~(i-vi)~~ and illustrations (Figures 1-3) detail how UNet^{SM} uses PCO_2 in the lung allocation score.

a. ~~(i)~~*Use of Arterial, Venous, or Capillary PCO_2 Values*

In UNet^{SM}, a center may enter a PCO_2 value from an arterial, venous, or capillary blood gas test. UNet^{SM} will convert a venous or

capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNet^{SM} will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNet^{SM} will use the PCO_2 value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet^{SM} will use the arterial value in the lung allocation score calculation.

b. ~~(ii)~~*Definition of Current PCO_2*
Current PCO_2 is the PCO_2 value with the most recent test date entered in UNet^{SM}.

c. ~~(iii)~~*Expiration of Current PCO_2 Value*
UNet^{SM} will evaluate a current PCO2 value as expired according to Policy 3.7.6.3~~.2.~~

d. ~~(iv)~~*Use of Normal Clinical Value for Current PCO_2*
The normal clinical value of PCO_2 is 40 mmHg. UNet^{SM} will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO_2 is less than 40 mmHg, missing, or expired.

e. ~~(v)~~*PCO2 Values Used in the Change Calculations*
There are two types of PCO_2 change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO_2 change is 15% or higher. In this calculation, UNet^{SM} will use highest and lowest values of PCO_2. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet^{SM} will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet^{SM} will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is: ~~**[(highest PCO_2 – lowest PCO_2)/lowest PCO_2]**~~

$$\frac{Highest\ PCO^2 - Lowest\ PCO^2}{Lowest\ PCO^2}$$

The threshold change maintenance calculation occurs after the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO_2 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 PCO_2 – lowest PCO_2)/lowest PCO_2]**~~

$$\frac{Current\ PCO^2 - Lowest\ PCO^2}{Lowest\ PCO^2}$$

UNet^{SM} will perform the threshold change maintenance calculation

either when the current PCO_2 value expires (Policy 3.7.6.3~~.2~~) or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the threshold change calculation. If a current PCO_2 value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO_2 value expires, UNet^{SM} will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current PCO_2 value for a candidate who has lost the impact from threshold change, UNet^{SM} will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the threshold change calculation, UNet^{SM} will *reapply* the impact from threshold change to the candidate's lung allocation score.

f. ~~(vi)~~*Impact of PCO_2 Threshold Change in the Lung Allocation Score*
A change in PCO_2 that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO_2 is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO_2 in the Lung Allocation Score

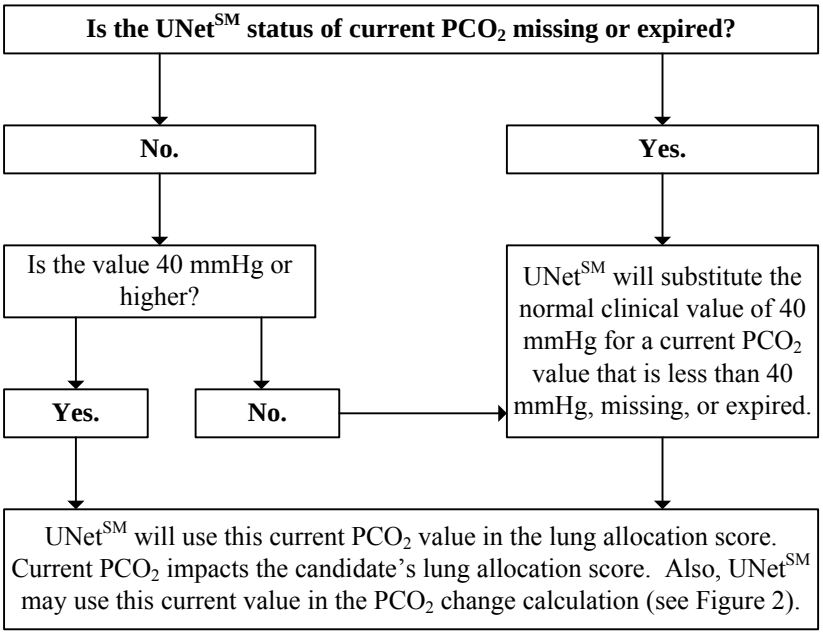


Figure 2

PCO_2 Threshold Change Calculation

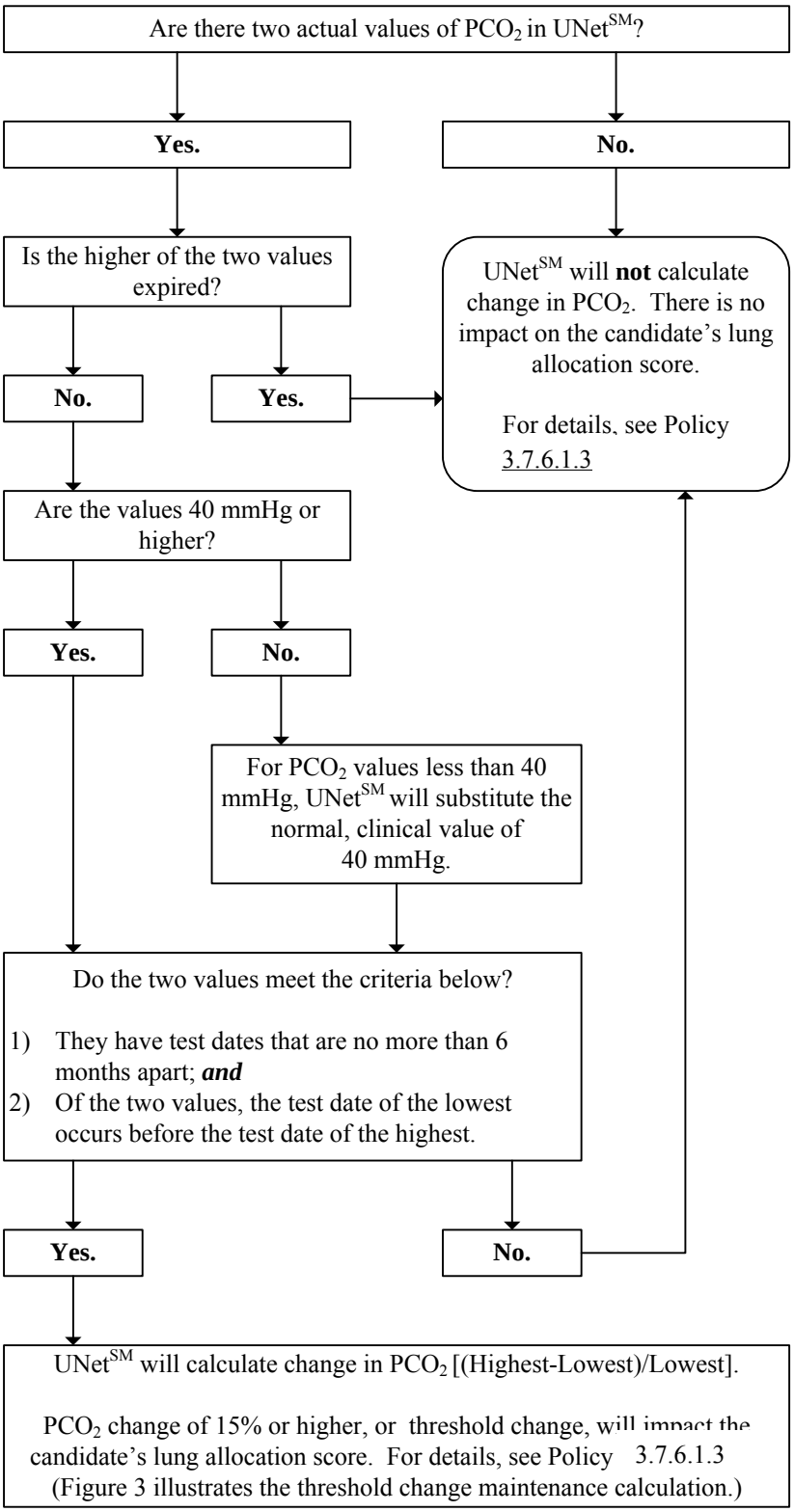
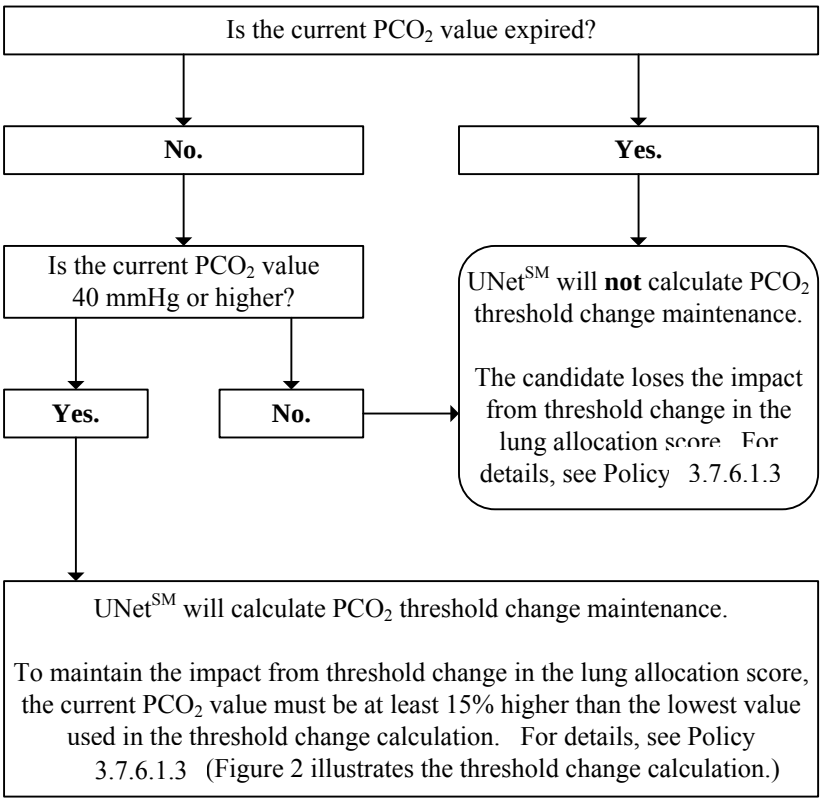


Figure 3
PCO_2 Threshold Change Maintenance Calculation



3.7.6.1.4 Bilirubin in the Lung Allocation Score (LAS)

~~*c. Bilirubin in the Lung Allocation Score*~~

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

a. ~~*(i)*~~ *Definition of Current Bilirubin*
Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet^{SM}. UNet^{SM} will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

b. ~~*(ii)*~~*Expiration of Current Bilirubin Value*
UNet^{SM} will evaluate a current bilirubin value as expired according to Policy 3.7.6.3~~.2.~~

c. ~~*(iii)*~~*Use of Normal Clinical Value for Current Bilirubin*
The normal clinical value of current bilirubin is 0.7 mg/dL. UNet^{SM}

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.

d. *~~(iv)~~Bilirubin Values Used in the Change Calculations (Group B Only)*
There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet^{SM} will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet^{SM} will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet^{SM} 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]~~

$$\frac{\textbf{Highest Bilirubin} - \textbf{Lowest Bilirubin}}{\textbf{Lowest Bilirubin}}$$

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]~~

$$\frac{\textbf{Current Bilirubin} - \textbf{Lowest Bilirubin}}{\textbf{Lowest Bilirubin}}$$

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

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

e. ~~(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~~3.7.6.1.4 (Bilirubin in the Lung Allocation Score) that are italicized were approved at the June 2009 Board of Directors Meeting. ~~shall be implemented pending Executive Committee approval of the related implementation plan. (Approved at the June 2009 Board of Directors Meeting.)~~***

3.7.6.1.5 Creatinine in the Lung Allocation Score (LAS)

~~e) Creatinine in the LAS Calculation~~

The LAS calculation uses two measures of creatinine: current creatinine (only for candidates who are at least 18 years of age), and increase in creatinine (for all candidates).

a. Current Creatinine
Current creatinine is the serum creatinine value from the most recent test date and time reported to the OPTN Contractor. The LAS calculation only uses current creatinine for candidates who are at least 18 years of age.

b. Increase in Creatinine
An increase in creatinine will influence a candidate's LAS only if it is at least 150%. The Increase-In-Creatinine calculation uses the highest and lowest values of creatinine. For this variable to impact a candidate's LAS, 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 the highest and lowest values cannot be more than 6 months apart. The Increase-In-Creatinine calculation can use an expired lowest value, but not an expired highest value. The equation for this increase-in-creatinine calculation is: ~~= (highest creatinine – lowest creatinine)/lowest creatinine.~~

$$\frac{\textit{Highest Creatinine} - \textit{Lowest Creatinine}}{\textit{Lowest Creatinine}}$$

If a candidate's LAS is influenced by an increase in creatinine, then the LAS calculation will assess whether to maintain that influence. To maintain the influence of the increase in creatinine, the candidate's current creatinine value must be at least 150% higher than the lowest value used in the increase-in-creatinine calculation. The equation for this maintenance calculation is: ~~= (current creatinine – lowest creatinine)/lowest creatinine~~

$$\frac{\textit{Current Creatinine} - \textit{Lowest Creatinine}}{\textit{Lowest Creatinine}}$$

If the current creatinine value expires ~~(Policy 3.7.6.3)~~ or a new creatinine value is entered, then the increase maintenance calculation will occur.

[...]

3.7.6.3 Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS)

When~~ listing~~ registering a candidate who is at least 12 years of age for lung transplantation, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in Tables 1 and 2 in Policy 3.7.6.1.1. ~~Policy 3.7.6.1, as well as other data required by the OPTN Contractor, pursuant to Policy 7.0 (Data Submission Requirements)~~. Data reported upon registering the candidate must be no more than six months older than the registration date. The transplant program must maintain source documentation for the reported data in the candidate's chart.

Except as noted in Policy 3.7.6.3.1, transplant programs must report to the OPTN Contractor each element of a candidate's clinical data ~~in UNet℠ by~~ at every "~~-~~six-month anniversary date~~"~~. ~~The LAS system defines a~~ A "six -month anniversary date~~," which~~ first occurs six months ~~from~~ after the date of initial ~~listing~~ registration, then every six months ~~there~~after. ~~The LAS system will consider a~~ A covariate's value ~~to be expired~~ expires if the covariate's test date is six-months older than the most recent six-month anniversary date. ~~The LAS system will consider a~~Actual values or estimated values for pulmonary pressures ~~to be~~ are valid until the transplant program ~~updates them with~~ submits new actual values or new estimated values to the OPTN Contractor according ~~pursuant~~ to Policy 3.7.6.4.

~~However, transplant programs do not need to report data obtainable only by heart catheterization every six months; instead, the t~~Transplant programs may determine~~ the frequency of updating~~ how often to update clinical data ~~obtainable~~ that must be obtained through heart catheterization. However, if a transplant program performs a heart catheterization~~ test~~ on the candidate during ~~the~~ any six month interval, then it must report the relevant results to the OPTN Contractor. The transplant program must maintain source documentation of all heart catheterization test results in the candidate's chart.

If values for certain covariates are missing, expired, or below a threshold as defined by Table 5, then the LAS calculation ~~will use a substituted~~ substitute normal or least beneficial values to calculate the candidate's LAS. ~~Table 5 lists the covariates for which the LAS calculation will use substituted data if the actual values are missing, expired, or below a certain threshold.~~ A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. Table 5 lists the normal and least beneficial values that will be substituted.

Table 5

Data Substituted for Missing ~~or~~, Expired, or Below Threshold Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the ~~substituted~~ threshold value:	**Then the LAS calculation will use this substituted value:**
Bilirubin: current	1.0 mg/dL if the actual value is missing, expired, or less than 1.0 mg/dL
Body mass index (BMI)	100 kg/m^2 if the actual value is missing or expired
Cardiac index	3.0 L/min/m^2 if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant model if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant model for candidates at least 18 years of age if the actual value is missing or expired 0~~.00~~ mg/dL in the post-transplant model for candidates less than 18 years of age if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Group D if the actual value is missing or expired, according to Policy 3.7.6.1.2(d)

If this covariate's value is missing, expired, or below the ~~substituted~~ threshold value:	**Then the LAS calculation will use this substituted value:**
Functional status	No assistance needed in the waiting list model if the actual value is missing or expired Some or total assistance needed in the post-transplant model if the actual value is missing or expired
Oxygen needed at rest	No supplemental oxygen needed in the waiting list model if the actual value is missing or expired 26.33 L/min in the post-transplant model if the actual value is missing or expired
PCO_2: current	40 mm Hg if the actual value is missing, expired, or less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six minute walk distance	4000 feet in the waiting list urgency model if the actual value is missing or expired 0 feet in the post-transplant survival model if the actual value is missing or expired

Programs are permitted to enter a medically reasonable estimated value ~~in the event~~ if 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~~ Before entering such estimated values, programs must ~~request review and~~ receive approval from the Lung Review Board, ~~to~~ which will 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~~ according to Policy 3.7.6.4.

~~**3.7.6.3 Candidate Variables in UNet℠.** Entry into UNet℠ 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 Reporting Data for Candidates with LASs of 50 or ~~Higher~~ Greater

A program must ~~update~~ report three key variables ~~in UNet℠~~ to the OPTN Contractor no more than 14 days after a candidate's LAS becomes ~~greater than~~ 50 or greater: ~~assisted ventilation, supplemental oxygen, and current PCO_2.~~

a. Assisted ventilation
b. Supplemental oxygen
c. Current PCO_2

If a program does not perform a PCO_2 test in that time, then it does not need to report this updated value in ~~UNet℠~~ to the OPTN Contractor. While the candidate's ~~score~~ LAS remains 50 or ~~higher~~ greater, ~~a~~ the program must continue to assess and report any observed change in the three clinical variables ~~no less frequently than~~ every 14 days ~~from the date of the previous assessment~~.

The transplant program must maintain source documentation for each assessment in the candidate's chart.

~~**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 UNet℠ 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.~~

~~UNet℠ defines a "six -month anniversary date," which first occurs six months from the date of initial listing, then every six months thereafter. UNet℠ 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 UNet℠.~~

~~UNet℠ 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 UNet℠ no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO_2. If a program does not perform a PCO_2 test in that time, then it does not need to update this value in UNet℠. 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.~~

[...]

3.7.9.2 Waiting Time Accrual for Lung Candidates ~~Age 12 and Older~~ at Least 12 Years of Age Following Implementation of Lung Allocation Score~~s~~ ~~Described in Policy 3.7.6~~ (LAS) System

[There are no changes to text that precede the struck paragraph below.]

~~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.~~

[...]

On October 16, 2012, the Committee met via LiveMeeting teleconference and unanimously voted to approve the post-public comment revisions made to the proposal since the September 5, 2012 Committee meeting (15-supported; 0-opposed; 0-abstained).

2. Policy 3.7.3 Allowing Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time Is Expiring

On November 9, 2010, the OPTN/UNOS Board of Directors (Board) approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. Clinicians may classify these candidates as Status 1A for 30 days. On November 15, 2011, the Board renewed this interim policy, with an expiration date of December 1, 2012.

On July 16, 2012, the Committee voted to allow the temporary TAH policy to expire on December 1, 2012. The Heart Subcommittee reexamined and reaffirmed the decision on August 13, 2012, and deliberations regarding communicating and implementing the expiration continued during the September 5, 2012 Committee meeting.

After examining data collected since the implementation of the provision in November 2010, the Committee noted that the number of candidates benefitting from this provision is significantly lower than the original number of candidates TAH manufacturers anticipated would participate in the clinical trial. (**Exhibit B**) The lack of data makes it difficult to determine whether outpatient TAH candidates are as medically urgent as other heart transplant candidates, including outpatient candidates implanted with ventricular assist devices (VADs). After comparing the TAH waiting list outcomes with waiting list outcomes for candidates implanted with VADs, the Committee determined it is difficult to draw strong conclusions about differences between TAH and VAD candidates because of how small the TAH candidate cohort is. There is not enough data to support a permanent TAH policy at this time.

During the September 5, 2012, meeting, the Committee agreed that policy gives ample notice to candidates of the expiration date, despite any information that may have been given to the candidates by other sources. Therefore, no additional Status 1A time can be accrued under the outpatient TAH provision when the policy expires on December 1, 2012.

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

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

Status	Definition
Status 1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for a 1A(b) candidate) and has at least one of the following devices or therapies in place: (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following: (i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being

implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.

(ii) total artificial heart;
(iii) intra-aortic balloon pump; or
(iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

~~[A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.]~~

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

[…]

Status 1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:

(a~~a~~) left and/or right ventricular assist device implanted; or
(b~~b~~) continuous infusion of intravenous inotropes.

~~[A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.]~~

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

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

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted to UNet℠ in order to list a candidate as Status 1B.

[There are no further changes to Policy 3.7.3]

The Committee submitted a memo to the October edition of the Communications e-newsletter to notify transplant programs more than 30 days before the policy expires, so that the transplant programs can register an outpatient TAH candidate as a Status 1A if they have not used up their Status 1A time yet. (**Exhibit C**) Additionally, the regions are being informed of the expiration during their Fall 2012 regional meetings.

The Heart Subcommittee will determine whether any further allocation policy changes should be developed for the TAH population.

3. Streamlining the Regional Review Board (RRB) and Lung Review Board (LRB) Guidelines and Policies

On August 28, 2012, the Executive Committee adopted modifications to the Heart and Liver RRB guidelines, the LRB guidelines, and Policies 3.7.3 (Adult Candidate Status), 3.7.4 (Pediatric Candidate Status), 3.7.6.2 (Candidates Age 0-11), and 3.7.6.4 (Lung Candidates with Exceptional Cases). The RRB Streamlining Workgroup, consisting of members from the Heart and Lung Subcommittees, as well as the Liver and Intestinal Organ Transplantation Committee, proposed the modifications.
Before the Workgroup proposed the modifications to the Executive Committee, the Heart and Lung Subcommittees received updates on the RRB streamlining project as it progressed, and submitted feedback. The Heart and Lung Subcommittees also reviewed the final version of the guidelines and policies, as proposed to the Executive Committee. (**Exhibit D**)

The RRB Streamlining Workgroup will continue to meet to identify and resolve other issues that may be streamlined across all three organ groups, and to work on programming requirements so that the guidelines and policies can be implemented as soon as possible.

4. Proposal to Remove the OPTN and UNOS Bylaws for the Combined Heart-Lung Transplant Program Designation

On July 16, 2012, the Committee voted in favor of distributing for public comment the *Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation* (20 supported; 0 opposed; 0 abstained).

The proposed change would remove Appendix J, the OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to transplant organs for which the transplant hospital has already been approved. Yet, aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. This combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

The proposal is co-sponsored by the Membership and Professional Standards Committee (MPSC), and was distributed for public comment on September 21, 2012.

5. Revising the Pediatric Heart Allocation Policies

During the September 5, 2012 Committee meeting, the Committee reviewed proposed revisions to the pediatric heart allocation policy since it was previously presented and explained by Dr. Steven Webber during the June 19, 2012 Joint Thoracic and Pediatric Committee teleconference. The policy language is being edited for clarity, and will be distributed during the Spring 2013 public comment cycle. Committee members identified certain issues that may be controversial once the policy is submitted for public comment.

For example, in the proposed policy, adult congenital heart disease candidates treated with intravenous inotropes will be prioritized before dilated cardiomyopathy candidates, because congenital heart disease candidates have higher mortality rates. Therefore, it might take much longer for a dilated cardiomyopathy candidate to receive a heart offer. Candidates diagnosed with dilated cardiomyopathy tend to have better post-transplant outcomes, so if they receive fewer offers, post-transplant survival rates may be impacted.

Additionally, in the proposed policy, candidates less than one year of age, regardless of isohemagglutinin titer, and candidates between at least one year of age, and registered prior to two years of age, with a isohemagglutinin titer of 1:16 or less, are eligible to receive heart offers from donors with incompatible blood group types. The proposal may be criticized because transplant programs that do yet perform blood group incompatible heart transplants for pediatric candidates, and therefore do not register pediatric candidates as eligible to receive blood group incompatible heart offers, will be disadvantaged. However, the policy may motivate transplant programs to start performing such transplants if they do not already do so.

Finally, in the proposed policy, candidates can no longer be registered *in utero*. In 2011 only one candidate was registered *in utero.* There have not been any *in utero* registrations in 2012 thus far.

The Committee voted unanimously to submit this policy proposal for public comment for the Spring, 2013 public comment cycle. (23 yes, 0 no, 0 abstentions).

6. Update on the Activities of the Heart Subcommittee

The Heart Subcommittee continues to:

- Revise the device-related infection and complication section in the adult heart policy

On June 29, 2012, the Heart Subcommittee met via LiveMeeting teleconference to discuss the *Proposal to Modify Policy 3.7.3 Status 1A(b)* to better define “device-related complications.” On September 5, 2012, Dr. Joe Rogers presented the proposal to the full Committee.

The Committee primarily discussed whether the modifications should be a distributed as a formal policy proposal or a guidance document. The Committee ultimately agreed that, in the interest of time, the Heart Subcommittee will finalize the proposed language and create a guidance document. However, it will continue to work on a policy proposal for Criterion (b) as well. The Heart Subcommittee will also examine the current heart status justification form and determine how it will mesh with the new guidance document.

- Evaluate the current Heart Allocation System to decide whether to develop a heart allocation score

The Heart Subcommittee continues to discuss the possibility of developing a heart allocation score. UNOS Research presented the Heart Subcommittee with data reports, including:

- Clinical Data Reported on Status 1A Justifications Forms for Criteria (d) (Inotropes) and Exceptions (**Exhibit E**)

- Adult Heart Status 1A VAD-Related Tabulations (**Exhibit F**)

Additionally, during the September 5, 2012, Committee meeting, UNOS Research Staff presented a Heart Allocation System Data Update. (**Exhibit G**) After reviewing the data, the Committee demonstrated a general satisfaction with the current heart allocation system, but identified areas that may need improvement. For example, the concept of a "critically ill" candidate may need to be updated. The Committee also expressed concern about the heart allocation system's tendency to benefit candidates implanted with VADs over all other Status 1A candidates, and requested data comparing transplant rates and survival rates for each category of candidate.

During its next meeting, the Heart Subcommittee will identify categories of candidates that are disadvantaged by the current heart allocation system, such as adult congenital heart disease candidates that may not be suitable for VAD implantation, and determine whether the current structure can be altered, rather than overhauled, to better accommodate these candidates.

7. Activities of the Lung Subcommittee

The Lung Subcommittee continues to:

- Develop Ex Vivo Lung Perfusion (EVLP) Allocation Policy

The Lung Subcommittee identified key participants for inclusion in an EVLP Workgroup. The Workgroup will be co-chaired by Dr. Kevin Chan and Dr. Mark Barr, and the Lung Subcommittee will receive updates on the Workgroup's progress. The Workgroup will primarily focus on allocation and utilization, adhering to the principles of equity while providing guidance and oversight to OPTN members.

The first EVLP Workgroup meeting occurred via LiveMeeting teleconference on October 2, 2012. The Workgroup briefly reviewed data provided by UNOS comparing the frequency with which lung offers are accepted, stratified by DSA and zones. For the next meeting, the Workgroup members requested additional data regarding the characteristics that were associated with donor lungs not being accepted, based on the information provided in the Deceased Donor Registration forms. Additionally, Workgroup members will obtain information about the allocation models currently being used by EVLP trial participants, as well as the criteria such participants require for acceptance of a lung for EVLP.

- Discuss the Heart-Lung Allocation Policy

After reviewing the proposed policy constructs the Committee previously sent to the Policy Oversight Committee, the Committee determined that the Lung Subcommittee should continue developing the policy based on the following "heart-centric" path:

"Heart-centric"

Status 1A
- If an OPO offers a heart to a Status 1A heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 55 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 55) in the local unit or in Zone A.

Status 1B
- If an OPO offers a heart to a Status 1B heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 45 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 45) in the local unit or in Zone A.

Status 2
- If an OPO offers a heart to a Status 2 heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 35 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 35) in the local unit or in Zone A.

"Lung-centric"

If the HL candidate has a LAS score greater than 45 and is a Status 2 heart by criteria, the transplant center has the option to list that candidate as a heart Status 1B-exception.

The Lung Subcommittee will continue to work on the details of "operationalizing" the policy proposal, which will likely include eliminating the heart-lung waiting list and clarifying the ambiguities in policy language so that OPOs know exactly how to allocate a heart-lung bloc. The Lung Subcommittee will reevaluate the data that has already been provided, and determine if any other data may help to fully develop the policy. The Lung Subcommittee will present a policy proposal to the Committee at the March 19, 2013 Committee meeting.

- Evaluate and Refine the LAS System: Data Report

The Committee reviewed data presented by UNOS demonstrating the impact of the LAS system since its implementation. (**Exhibit H**) Most notably, the mortality rate amongst candidates in the highest LAS grouping (70 or higher) has increased between 2009 and the

present. The Committee hypothesized the increase in mortality rate could be attributed to the increased rate of performing lung transplants on candidates older than 65 years of age. However, there has also been a decrease in deaths on the waiting list for all other LAS groupings, which may be related to the number of candidates on mechanical ventilation. The Lung Subcommittee will more closely evaluate the data, and identify possible causes for the increase in death rates.

- Evaluate and Refine the LAS System: Clarification for Data Reporting

The UNOS Membership department forwarded the Lung Subcommittee the following email from a member:

> I am writing to ask your input and guidance about the criteria for the allocation of lungs for transplant. A patient who was seen in our center also visited another center in-state. According to the patient, she was told her right heart catheterization at their center would be performed during exercise. The consequence is that this may increase pulmonary artery pressures compared to that at rest. My issue thus relates to the use of the higher pulmonary pressures obtained with exercise for reporting in the lung allocation score (resulting in a higher LAS score). The UNOS policies I have reviewed for organ allocation do not provide any guidance regarding the use of exercise physiology for the LAS, however, I have been told informally that this practice is not permitted.

The Subcommittee submitted a memo to the October edition of the UNOS Communications e-newsletter, clarifying that hemodynamic measures should be taken at rest, rather than during exercise, to honor the intent of the LAS. Additionally, the Lung Subcommittee added clarifying language to the post-public comment LAS Modification proposal, in order to clarify the intent of the policy without substantively changing it. The *Proposal to Revise the Lung Allocation Score (LAS) System* contains these changes.

- Evaluate and Refine the LAS System: ECMO Data Collection

Based on the following scenario presented by a Lung Subcommittee member, the Subcommittee discussed whether a candidate, who is on ECMO and is then extubated, is still on “mechanical ventilation” for UNOS policy purposes, and how FiO_2 should be measured:

> A question came up last night from my side of the US that I wanted to clarify with you regarding policy for lung candidates who are supported with ECMO prior to transplant. Many centers for obvious reasons don't adjust the scores when patients' FiO2 comes down on ECMO or claiming it's equivalent to being on 100% O2 so the LAS remains high. Other centers are keeping their high scores from ventilation with high FIO2 claiming they don't have to update for two weeks. As we have talked about in past meetings, there was no ECMO data in the set used to build the LAS and the odds ratio for acute mortality is extremely high in the UNOS data, so is it your feeling that it is OK for centers to simply come up with the highest score they can? An alternative would be for everyone to submit for an exception but I have no idea how many exceptions like that are requested per year or what % of ECMO supported patients that mechanism is used.

Currently, the Department of Evaluation and Quality (DEQ) considers a candidate, who is on ECMO and is extubated, to be mechanically ventilated, but expects to see true FiO_2 measures. The Committee previously decided to require all candidates who are listed on ECMO to apply to the Lung Review Board (LRB) for an exception in order to capture such data. But, this approach has proven unsuccessful, as candidates on ECMO are likely to have high LAS scores and their physicians are therefore unlikely to request an exception for a higher LAS.

The Subcommittee is concerned that as ECMO use grows, there may be differences in candidates' medical urgencies depending on the type of ECMO used. A patient on ambulatory ECMO may not be as medically urgent as a patient on traditional ECMO, and the Subcommittee wants to ensure that they have the appropriate data to make policy for this potential situation.

The Subcommittee requested data on the LAS scores and FiO_2 levels for all candidates who were transplanted off of ECMO over the last three years. The Subcommittee will particularly focus on candidates who are on ECMO but are extubated. After analyzing the data, the Subcommittee may consider different policy solutions for stratifying ECMO candidates and collecting data on them.

8. Initiating Work on Recently Approved Projects

In June 2012, the Board of Directors approved the following project proposals:

- Develop ABO Incompatible Lung Allocation Policy for Pediatric Candidates
- Automate the HLA Section in Policy 3.7.1.2.1.xiii (Human leukocyte antigen (HLA) type if requested by the transplant center

The Lung Subcommittee previously discussed transplanting ABO-incompatible lungs for pediatric candidates during its February 28, 2012, meeting, and determined that Subcommittee needs to evaluate the following data before continuing:

- Median time to transplant among the very young lung transplant candidates;
- Waiting list mortality of infants waiting for lung transplantation in the current era; and,
- Frequency of donated infant lungs that are not matched.

The Lung Subcommittee has not yet resumed work on this project, but anticipates doing so to capitalize on the momentum from the *Proposal to Change Pediatric Heart Allocation Policy,* which also includes ABO-incompatible organ allocation policy.

Additionally, the Committee has yet to begin work on automating the HLA policy. The project will likely to be delegated to the Heart Subcommittee once the *Proposal to Modify Policy 3.7.3 Status 1A(b)* is distributed for public comment.

9. Review of Heart Regional Review Board (RRB) Denial to Grant Status 1A Exception Extension Request

The Committee reviewed a case from May 2012, in which a transplant center requested an extension from the RRB to continue to list a candidate as Status 1A by exception. The RRB denied the request because the candidate did not have sustained ventricular tachycardia, or sustained need for shocks. The Committee reviewed the transplant center's request and supporting evidence, but ultimately agreed with the RRB's decision to deny the extension request based on the information available to the RRB. The Committee voted in favor of the RRB's decision (18 supported; 0 opposed; 1 abstained).

10. Review of Wait Time Modification Requests

During the July 16, 2012, meeting, the Committee reviewed a waiting time modification request for a candidate due to a clerical error on the part of the transplant center. The Committee agreed that for clerical errors, the Committee generally assumes that the requesting center made an honest mistake and therefore will approve requests to modify the candidate's waiting time. The Committee voted in favor of reinstating the candidate's time (19 yes; 0 no; 0 abstained).

During the September 5, 2012 meeting, the Committee reviewed two wait time modification cases that originated in the same transplant program. Two candidates' last names began with the same letter, and were seen for appointments on the same day. When their charts were updated, one candidate's status was incorrectly downgraded from Status 2 to Status 7, while the candidate whose registration should have been downgraded to Status 7 remained Status 2. The error was discovered on August 25, 2012, and the program sought the Committee's permission to reinstate the proper waiting times, at the proper statuses, for each candidate.

The Committee was concerned that the mistake was careless, but agreed it did not meet "egregious" levels. Rather, this was a clerical error. The Committee therefore voted unanimously to allow the program to restore the correct waiting time at the correct status for each of the candidates. (23 yes; 0 no; 0 abstentions).

The Committee also discussed more efficient ways for reviewing cases that are not direct appeals from the review boards. Often, there are long delays between the time the Committee is contacted to review a case, and the time the Committee actually meets to discuss it. This delay could be detrimental to a candidate if the error or delay causes the candidate to miss an organ offer.

The Committee voted unanimously to empower the Committee's leadership (the Chairman, the Vice Chairman, and the Chairmen of each Subcommittee) to review cases involving clerical mistakes within 72 hours of when they are received, and if they identify broader concerns in the case, they will refer the case to the whole Committee. (23 yes; 0 no; 0 abstentions) The leadership will be able to quickly respond to clerical mistakes in order to benefit the candidate, and will attempt to recognize disconcerting patterns of behavior from "repeat offender" programs, that may require referral to the Membership and Professional Standards Committee (MPSC).

Thoracic Organ Transplantation Committee	July 16, 2012 Meeting Via Teleconference and Internet	
Name	**Position**	**Attendance**
Steven Webber MD	CHAIR	By phone
Joseph Rogers MD	VICE CHAIR	By phone
Tajinder Singh MD	REGION 1	
Linda Bogar MD	REGION 2	
Seth Force MD	REGION 3	
Shelley Hall MD	REGION 4	By phone
Gordon Yung MD	REGION 5	By Phone
Mariska Kemna MD	REGION 6	By Phone
Richard Daly MD	REGION 7	By phone
Joseph Cleveland Jr. MD	REGION 8	By phone
Leway Chen MD	REGION 9	By phone
Brad Dyke MD	REGION 10	By phone
Timothy Whelan MD	REGION 11	By phone
Luis Angel MD	AT LARGE	By phone
Nancy Blumenthal MSN, CRNP	AT LARGE	By phone
Kevin Chan MD	AT LARGE, Lung Subcommittee Chair	By phone
Ladora Dils RN, CPTC	AT LARGE	
Kevin Dushay MD	AT LARGE	By phone
Maryl Johnson MD	AT LARGE	
Gary A. Visner, MD	AT LARGE	By phone
William Mahle MD	AT LARGE	By phone
Laurie P. Loza, RN	AT LARGE	By phone
Dan Meyer MD	AT LARGE, Heart Subcommittee Chair	By phone
Mark Barr, MD	Ex Officio	By phone
Damian Nueberger PhD	AT LARGE	
Mark Zucker MD, JD	AT LARGE	
Ba Lin, MPH	HRSA Representative	By phone
Monica Lin, PhD	HRSA Representative	By phone
Monica M. Colvin-Adams, MD	SRTR Liaison	By phone
Marshall Hertz, MD	SRTR Liaison	
Brooke Heubner, MD	SRTR Liaison	By phone
Melissa Skeans, MS	SRTR Liaison	By phone
Maryam Valapour, MD	SRTR Liaison	By phone
Ajay Israni, MD, MS	SRTR Liaison	
Tabitha Leighton	SRTR Liaison	By phone
Leah Edwards, PhD	UNOS Staff	By phone
Liz Robbins, Esq.	UNOS Staff	By phone
James Alcorn	UNOS Staff	By phone
Elizabeth Miller	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone

Thoracic Organ Transplantation Committee	September 5, 2012 Meeting Chicago, Illinois	
Name	**Position**	**Attendance**
Steven Webber MD	CHAIR	Present
Joseph Rogers MD	VICE CHAIR	Present
Tajinder Singh MD	REGION 1	Present
Linda Bogar MD	REGION 2	Present
Seth Force MD	REGION 3	Present
Shelley Hall MD	REGION 4	Present
Gordon Yung MD	REGION 5	Present
Mariska Kemna MD	REGION 6	Present
Richard Daly MD	REGION 7	Present
Joseph Cleveland Jr. MD	REGION 8	Present
Leway Chen MD	REGION 9	By phone
Brad Dyke MD	REGION 10	Present
Timothy Whelan MD	REGION 11	Present
Luis Angel MD	AT LARGE	Present
Nancy Blumenthal MSN, CRNP	AT LARGE	By phone
Kevin Chan MD	AT LARGE, Lung Subcommittee Chair	Present
Ladora Dils RN, CPTC	AT LARGE	Present
Kevin Dushay MD	AT LARGE	Present
Maryl Johnson MD	AT LARGE	Present
Gary A. Visner, MD	AT LARGE	Present
William Mahle MD	AT LARGE	Present
Laurie P. Loza, RN	AT LARGE	Present
Dan Meyer MD	AT LARGE, Heart Subcommittee Chair	Present
Mark Barr, MD	Ex Officio	
Damian Nueberger PhD	AT LARGE	Present
Mark Zucker MD, JD	AT LARGE	Present
Ba Lin, MPH	HRSA Representative	By phone
Monica Lin, PhD	HRSA Representative	Present
Monica M. Colvin-Adams, MD	SRTR Liaison	Present
Marshall Hertz, MD	SRTR Liaison	
Brooke Heubner, MD	SRTR Liaison	Present
Melissa Skeans, MS	SRTR Liaison	By phone
Maryam Valapour, MD	SRTR Liaison	Present
Ajay Israni, MD, MS	SRTR Liaison	
Tabitha Leighton	SRTR Liaison	By phone
Leah Edwards, PhD	UNOS Staff	Present
Liz Robbins, Esq.	UNOS Staff	Present
James Alcorn	UNOS Staff	By phone
Elizabeth Miller	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Brian Shepard	UNOS Staff	Present
Chad Waller	UNOS Staff	Present
Lee Goodman	UNOS Staff	Present
Aaron McCoy	UNOS Staff	Present
Michelle Orive	Rush to Live Organization President	Present