

## *Public Comment Proposal*

# Refine Lung Data Fields

*OPTN Lung Transplantation Committee*

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# Refine Lung Data Fields

<i>Affected Policies:</i>	<i>Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old</i> <i>Policy 10.1.F: The LAS Calculation</i>
<i>Sponsoring Committee:</i>	<i>Lung Transplantation</i>
<i>Public Comment Period:</i>	<i>April 27, 2021 – May 27, 2021</i>

## Executive Summary

As part of continuing improvement efforts to improve the organ allocation system, staff conduct gap analyses of allocation policies and the way data is collected and used for allocation in UNet<sup>SM</sup>. During the gap analysis focused on lung allocation, several areas for clarification were identified and prioritized for implementation in conjunction with the changes to the lung allocation score (LAS) that were approved at the December 2020 OPTN Board of Directors Meeting. The previously approved proposal, “*Updated Cohort for Calculation of the Lung Allocation Score (LAS)*,”<sup>1</sup> is planned for implementation in the fall of 2021. This project focuses on the most urgent changes that can improve the application programming interface (API) integration and implementation of this scheduled LAS update. These proposed changes are related to the use of body mass index (BMI), pulmonary fibrosis, and bronchiolitis in the LAS. This proposal will change the way dates are collected when a transplant hospital updates a candidate’s height or weight, which are used to calculate BMI, and will change which specific sub-diagnoses receive coefficient adjustments in calculating LAS.

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<sup>1</sup> Notice of OPTN Policy Changes. *Updated Cohort for Calculation of the Lung Allocation Score (LAS)*. December 2020. Available at <https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf>.

## Background

The OPTN conducts an annual analysis on at least one organ group as part of continuous quality efforts. During a gap analysis focused on lung allocation, several areas for clarification were identified. This proposal focuses on the most urgent changes that can improve API integration and fit in with the implementation of previously approved LAS updates. The changes in this proposal were prioritized for implementation in conjunction with the changes to the LAS that were approved at the December 2020 Board meeting because of the efficiencies that can be gained by implementing the changes at the same time. Other areas for improved alignment were identified and assigned different priorities. For instance, some changes will be addressed as part of an upcoming proposal for continuous distribution.

The changes are related to the way the LAS is calculated for certain candidates. The LAS is a model based on significant variables that are predictive of a candidate's expected 1-year waitlist survival and expected 1-year post-transplant survival. It is used in lung allocation to rank candidates. A higher expected waitlist mortality and lower expected post-transplant mortality corresponds to a higher LAS. Coefficients are used in the calculation of LAS to weigh the relevant variables and are based on analysis of transplant candidates and recipients performed by the Scientific Registry of Transplant Recipients (SRTR). Coefficients are assigned based on variables such as laboratory values, diagnosis group, specific diagnosis, or a combination of values and diagnosis.<sup>2</sup>

## Purpose

This proposal clarifies data entry and the impact of specific diagnoses for LAS. Changes to the reporting will ensure that data is reported consistently, and aid in candidates with similar diagnoses or lab results being treated the same way. Creating distinct date fields for the components of BMI (height and weight) will address some confusion regarding how to update values when they were not collected on the same date, as well as allow for more seamless uploads of that data from electronic medical records (EMR) through the use of APIs. Combining two of the diagnosis options for candidates with pulmonary fibrosis ("secondary pulmonary fibrosis" and "pulmonary fibrosis: other") will reduce ambiguity in reporting.

For candidates with diagnoses of "COVID-19: pulmonary fibrosis" or "constrictive bronchiolitis," policy is not clear that specific diagnosis coefficients apply, which could lead to confusion for candidates about how their LAS is calculated. Adding specific language<sup>2</sup> stating that the coefficient applies when there is a diagnosis of "COVID-19: pulmonary fibrosis" or "constrictive bronchiolitis" will ensure that the system is more transparent and equitable.

The Lung Transplantation Committee (Committee) submits this project for approval pursuant to the authority of the OPTN Final Rule, 42 CFR §121.4(a)(1), which states "The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies... for the equitable allocation of cadaveric organs." This project revises allocation policies for deceased donor lungs.

This project is submitted under the authority of 42 C.F.R §121.11(a)(1)(i)-(iii), which states the OPTN shall "(i) Maintain and operate an automated system for managing information about transplant

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<sup>2</sup> All reported lung diagnoses are assigned a diagnosis group A-D with diagnoses that have similar waitlist mortality and post-transplant survival expectations. OPTN Policy 10.1.F The LAS Calculation.

candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants; (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients; (iii) Operate, maintain, receive, publish, and transmit such records and information electronically..." This project will improve the OPTN's maintenance of these records of transplant candidates by refining the fields for which they must provide information.

## Overview of Proposal

The Committee proposes:

1. Replacing the current single date field for height, weight, and BMI with distinct date fields for height and weight
2. Specifying that only the weight is required to be updated every 6 months in order to keep the BMI current
3. Removing the diagnosis option of “secondary pulmonary fibrosis”
4. Utilizing the same coefficient when a candidate’s diagnosis is “pulmonary fibrosis: other” and when the candidate’s diagnosis is “COVID-19: pulmonary fibrosis”
5. Clarifying that the coefficient currently used when a candidates’ diagnosis is “obliterative bronchiolitis” is also used when the candidate’s diagnosis is “constrictive bronchiolitis”
6. Clarifying that when a candidate’s mean PA pressure is missing, it is treated as if the mean PA pressure was 30 or less
7. Updating labels for three diagnoses<sup>3</sup>

### BMI

BMI is used in the LAS calculation and is collected in Waitlist<sup>SM</sup> in two fields - height and weight. However, there is only one date field for the two values. Members have reported uncertainty about how to properly report when height and weight were not collected on the same date, or when they only collected a new weight. Additionally, APIs are currently under development for these data, and there are challenges associated with mapping to member electronic records because EMRs typically record a date for each value. The Committee proposes removing the combined field, and adding two separate fields – one for the date the height was collected and another for the date the weight was collected.

*Policy 10.1.E: Priority and Clinical Data Update Schedule for Candidates at Least 12 Years Old* requires that transplant hospitals update clinical data used in the LAS calculation every 6 months. Since height is unlikely to change for most lung candidates within a 6 month timeframe, the Committee proposes that in order to update the BMI, only the weight must be updated every 6 months, and not the candidate’s height. With the ability to update height independently, transplant hospitals would be able to update height as needed and would have an incentive to do so because of the positive impact of the taller height on BMI.

### Pulmonary Fibrosis

#### *Removing the diagnosis option of “Secondary pulmonary fibrosis”*

There are four diagnoses options in Waitlist<sup>SM</sup> related to pulmonary fibrosis:

1. “Pulmonary fibrosis: idiopathic pulmonary fibrosis (IPF)”
2. “Pulmonary fibrosis: other specify cause”

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<sup>3</sup> The Committee voted (12 approve, 0 abstain, 0 deny) to submit this proposal for public comment on April 1, 2021.

3. “Secondary pulmonary fibrosis: specify cause”
4. “COVID-19: Pulmonary fibrosis”

Of these, only “pulmonary fibrosis: other specify cause” receives the impact of a diagnosis-specific coefficient when LAS is calculated.

The Committee proposes combining the options “secondary pulmonary fibrosis: specify cause” and “pulmonary fibrosis: other specify cause” because the two options overlap and cause confusion about which is appropriate for a given candidate. Between 1/1/2018 and 2/28/2021, there were 45 candidates added to the waiting list with a diagnosis of “secondary pulmonary fibrosis: specify cause” reported on the Transplant Candidate Registration (TCR), and the specified text was largely similar to diagnoses supplied for candidates listed as “pulmonary fibrosis: other specify cause.”<sup>4</sup> Selection between the two options affects a candidate’s LAS because “secondary pulmonary fibrosis: specify cause” does not receive the additional diagnosis coefficient that “pulmonary fibrosis: other specify cause” does, which in turn, will affect the candidate’s order on a match run.

### *Application of “Pulmonary fibrosis: other specify cause” coefficient to “COVID-19: pulmonary fibrosis”*

In OPTN policy, *Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients* lists a waiting list coefficient for “pulmonary fibrosis: other specify cause (Diagnosis Group D only).” The Committee proposes specifying that the “Pulmonary fibrosis: other specify cause” and “COVID-19: Pulmonary fibrosis” receive the coefficient adjustment to LAS for waiting list mortality. These changes would make a distinction between “idiopathic pulmonary fibrosis,” which does not receive the adjustment, and all other pulmonary fibrosis diagnoses, which would. This is in alignment with the current placement of “idiopathic pulmonary fibrosis” in Group A and all other pulmonary fibrosis diagnoses in Group D.

## Bronchiolitis

“Obliterative bronchiolitis” and “constrictive bronchiolitis” are both listed as Group D diagnoses and assigned the corresponding diagnosis group coefficient in policy.<sup>5</sup> When the LAS coefficients were determined based on analysis of the impact of variables on expected waitlist mortality and post-transplant survival, constrictive and obliterative bronchiolitis were grouped together as a single diagnosis, and the system is programmed to assign both diagnoses the coefficient when LAS is calculated.<sup>6</sup> However, policy only lists the adjustment for “obliterative bronchiolitis” (see *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients*). This proposal would make it more clear that the coefficient adjustment applies for the post-transplant survival calculation to all

<sup>4</sup> Only 5 candidates had a diagnosis listed under “secondary pulmonary fibrosis” that was not also listed for another candidate who was listed as “pulmonary fibrosis: other.” One of the five was listed as COVID-19, before a specific diagnosis option was created for COVID-19: pulmonary fibrosis. OPTN data. March 12, 2021.

<sup>5</sup> Because a candidate’s diagnosis has a bearing on their expected waitlist and post-transplant mortality, the diagnosis is included in the LAS calculation. The diagnoses are organized into four groups (A-D) of similar types of disease, and a different value is assigned for each of the groups. Certain diagnoses have more specific data available, and in those cases, the score receives a further adjustment that is specific to that diagnosis. *OPTN Policy 10.1.F The LAS Calculation*.

<sup>6</sup> OPTN Briefing Paper, *Proposal to Revise the Lung Allocation Score (LAS) System*. 2012.

candidates registered with either “obliterative bronchiolitis” or “constrictive bronchiolitis.”<sup>7</sup> This will address an unintentional exclusion in the policy language.

## Sarcoidosis

Currently, mean pulmonary arterial (PA) pressure is not used directly in the calculation of LAS, but is used to determine in which diagnosis group for candidates with sarcoidosis will be placed.<sup>8</sup> When the mean pressure is above 30, candidates with the sarcoidosis diagnosis are placed in group D, and when it is 30 or below, candidates with sarcoidosis are in group A. This proposal would clarify that when the mean pressure is missing, that variable is treated as 30 or below, and the candidate is placed in group A and given the same coefficient adjustment as other candidates with sarcoidosis with mean pressure of 30 or below. This is currently how LAS is calculated for these patients, and the policy change will make that clearer.

## Labels

There are three diagnoses that are currently labeled slightly differently in policy from their label in Waitlist<sup>SM</sup> and Transplant Information Electronic Data Interchange<sup>®</sup>(TIEDI). The Committee proposes changing the labels for three diagnoses to align with more current terminology, which is already being used in the system.

Current diagnosis label in policy	New diagnosis label
Surfactant protein B mutation	Surfactant protein B deficiency
Surfactant protein C mutation	Surfactant protein C deficiency
Primary pulmonary hypertension/pulmonary arterial hypertension	Pulmonary hypertension/pulmonary arterial hypertension

## NOTA and Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”<sup>9</sup> This project revises allocation policies for deceased donor lungs through several adjustments to fields that affect the calculation of the LAS.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8.” This proposal is consistent with §121.8 because it:

<sup>7</sup> The wait list mortality adjustments for obstructive bronchiolitis were approved for removal in the *Updated Cohort for Calculation of the Lung Allocation Score (LAS)* policy changes in December 2021. These changes would be implemented at the same time as this removal, and therefore there is no need to align any wait list mortality adjustment.

<sup>8</sup> Mean PA pressure is distinct from PA systolic pressure at rest, prior to any exercise. Mean PA pressure is not included in the LAS calculation as an independent variable. However, PA systolic pressure at rest is assigned a coefficient and directly used.

<sup>9</sup> 42 CFR §121.4(a).

- **Is based on sound medical judgment**<sup>10</sup>: This proposal is an evidenced-based change relying on medical judgment based on reviewing data showing that the specific diagnoses provided in response to the “specify” prompts for “secondary pulmonary fibrosis” and “pulmonary fibrosis: other” largely overlap, and documentation showing original intent for application of coefficients.
- **Seeks to achieve the best use of donated organs**<sup>11</sup>: This proposal ensures that organs are allocated and transplanted according to medical urgency by making sure similarly situated candidates receive the same waitlist mortality calculation. This proposal ensures that adjustments for waiting list mortality for candidates with diagnoses of “secondary pulmonary fibrosis”, “pulmonary fibrosis: other”, and “COVID-19: pulmonary fibrosis” are aligned with the expected waiting list mortality for non-idiopathic pulmonary fibrosis. It also aligns the adjustments for post-transplant survival for candidates with diagnoses of “obliterative bronchiolitis” and “constrictive bronchiolitis” are aligned to the appropriate expected post-transplant survival.
- **Is designed to avoid futile transplants**<sup>12</sup>: This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes. It takes into account a candidate’s likelihood of survival post-transplant by aligning the adjustments for post-transplant survival for candidates with “constrictive bronchiolitis” and sarcoidosis with modeled post-transplant survival expectations.
- **Is designed to...promote patient access to transplantation**<sup>13</sup> by giving similarly situated candidates equitable opportunities to receive an organ offer. Candidates with the same medical urgency and similar distance to the donor hospital will have equitable opportunities to receive an organ offer through this proposal because it will provide the same diagnosis-specific adjustments for candidates with similar diagnoses (aligning “obstructive bronchiolitis” and “constrictive bronchiolitis”, as well as aligning non-idiopathic pulmonary fibrosis, whether it is reported as “secondary pulmonary fibrosis” or “pulmonary fibrosis: other”).

Although the proposal outlined in this proposal addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Is designed to avoid wasting organs<sup>14</sup>
- Promotes the efficient management of organ placement<sup>15</sup>
- Is not based on the candidate’s place of residence or place of listing<sup>16</sup>
- Preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,<sup>17</sup> and it is specific to an organ type, in this case, lungs.<sup>18</sup>

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.<sup>19</sup> The changes to BMI collection dates, obliterative and constrictive

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<sup>10</sup> 42 CFR §121.8(a)(1).

<sup>11</sup> 42 CFR §121.8(a)(2).

<sup>12</sup> 42 CFR §121.8(a)(5).

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> Ibid.

<sup>16</sup> 42 CFR §121.8(a)(8).

<sup>17</sup> 42 CFR §121.8(a)(3).

<sup>18</sup> 42 CFR §121.8(a)(4).

<sup>19</sup> C.F.R. § 121.8(d).



bronchiolitis, and sarcoidosis will not treat any candidate less favorably, and therefore no transition procedures are recommended for these candidates. With the changes to which pulmonary fibrosis candidates will be affected by the coefficient adjustment to their LAS score, some of the candidates with these diagnoses may have a higher or lower LAS if these proposed policies are approved by the Board of Directors.<sup>20</sup> However, the anticipated changes in any candidate's LAS as a result of the coefficient changes is small and the Committee chose not to have a transition period, but rather to apply the new coefficient for these candidates immediately upon implementation.

## Implementation Considerations

### Member and OPTN Operations

Changes to Waitlist<sup>SM</sup> will be implemented in fall of 2021, in tandem with changes that were included in the *Updated Cohort for Calculation of the Lung Allocation Score (LAS)* approved by the Board of Directors in 2020. Candidates listed with a diagnosis of "secondary pulmonary fibrosis" will be converted to "pulmonary fibrosis: other" when the changes are implemented. Candidates with diagnoses whose coefficients will change will experience a change in their LAS upon implementation.

The single BMI date field on the transplant candidate registration (TCR), transplant recipient registration (TRR), and transplant recipient follow-up (TCR) forms for pediatric recipients in TIEDI will be updated with the two new date fields upon approval from OMB.<sup>21</sup>

#### *Operations affecting Transplant Hospitals*

These changes, coupled with the API creation planned for implementation at the same time will create the ability for transplant hospitals to upload height and weight updates. Some candidates may experience changes in their LAS scores as a result of the updates to coefficients.

This proposal may require the submission of official OPTN data that are not presently collected by the OPTN. The collection of official OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB). The OMB approval process may impact the implementation timeline.

## Projected Fiscal Impact

### **Transplant Hospitals**

There is minimal expected impact for transplant hospitals that perform lung transplants to update workflows and train staff on changes to data entry. These changes are expected to improve consistency in and equity of the LAS calculation for lung candidates.

### **OPOs**

There is no expected fiscal impact for OPOs.

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<sup>20</sup> Based on a snapshot of listings on 1/15/2021, there were four candidates who, using the current LAS calculation would be affected by the coefficient change for "COVID-19: pulmonary fibrosis". Of those, three would see scores decrease, and the highest decrease would be less than 3.5 point change in their LAS."

<sup>21</sup> There is no corresponding date field on these forms for adult lung recipients.

## Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

### *Projected Impact on the OPTN*

The proposal is a demand-sized implementation request, requiring an estimated 125 hours to implement.

## Post-implementation Monitoring

### Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”<sup>22</sup>

The proposed language will not change the current routine monitoring of OPTN members. Site surveyors will continue to verify that data reported for LAS variables in UNet is consistent with source documentation in the candidate's medical record.

### Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”<sup>23</sup>

This proposal will be implemented in conjunction with the *Updated Cohort for Calculation of the Lung Allocation Score (LAS)* proposal. The OPTN Lung Committee will follow the monitoring plan as outlined in the *Updated Cohort for Calculation of the Lung Allocation Score (LAS)* proposal.<sup>24</sup>

The OPTN and Scientific Registry of Transplant Recipients (SRTR) contractors will provide any additional analyses outside of the regular monitoring plan as requested after implementation.

## Conclusion

This proposal would clarify data entry and the impact of specific diagnoses for LAS. Creating distinct date fields for the components of BMI (height and weight) will address some confusion regarding how to update values when they were not collected on the same date, as well as allowing for more seamless uploads of that data from EMRs through the use of APIs. Combining two of the diagnosis options for candidates with pulmonary fibrosis will reduce ambiguity in reporting and provide for equitable treatment of similar candidates. Adding specific language stating that the coefficient applies when there is a diagnosis of “COVID-19: pulmonary fibrosis” or “constrictive bronchiolitis” will ensure that the system is more transparent and equitable.

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<sup>22</sup> 42 CFR §121.8(a)(7).

<sup>23</sup> 42 CFR §121.8(a)(6).

<sup>24</sup> <https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf>

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN clinical data corresponding with to the covariates shown in *Table 10-3: Waiting List Mortality Calculation: Covariates and Their Coefficients* and *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN LAS covariate clinical data for every covariate in *Table 10-3* and *Table 10-4* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six-month period occurring every six months thereafter.

A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in *Policy 10.2.B.iii: Estimated Values Approved by the LRB*.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB*. Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program

41 performs a heart catheterization test on the candidate during the six month interval, then it  
 42 must report the data to the OPTN.

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 44 If values for certain covariates are missing, expired, or below the threshold as defined by *Table*  
 45 *10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the  
 46 candidate’s LAS. A normal value is one that a healthy individual is likely to exhibit. A least  
 47 beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal  
 48 and least beneficial values that will be substituted.

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 50 **Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS**

If this covariate’s value:	Is:	Then the LAS calculation will use this substituted value:
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL
<u>Height or weight to determine BMI</u>	Missing or expired	100 kg/m <sup>2</sup>
<u>Weight to determine BMI</u>	Expired	100 kg/m <sup>2</sup>
Cardiac index	Missing	3.0 L/min/m <sup>2</sup>
Continuous mechanical ventilation	Missing or expired	No mechanical ventilation in the waiting list model  Continuous mechanical ventilation while hospitalized in the post-transplant survival measure
Creatinine: serum	Missing or expired	0.1 mg/dL in the waiting list model  40 mg/dL in the post-transplant survival measure for candidates at least 18 years old  0 mg/dL in the post-transplant survival measure for candidates less than 18 years old
Functional status	Missing or expired	No assistance needed in the waiting list model  Some or total assistance needed in the post-transplant survival measure
Oxygen needed at rest	Missing or expired	No supplemental oxygen needed in the waiting list model

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
		26.33 L/min in the post-transplant survival measure
PCO <sub>2</sub>	Missing, expired, or less than 40 mm Hg	40 mm Hg
Pulmonary artery (PA) systolic pressure	Missing or less than 20 mm Hg	20 mm Hg
Six-minute-walk distance	Missing or expired	4,000 feet in the waiting list urgency measure  0 feet in the post-transplant survival measure

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### 10.1.F The LAS Calculation

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

- Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waiting List Urgency Measure.
- Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

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

**Table 10-2: LAS Calculation Values**

Where...	Includes...
$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$	<p>PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.</p> <p><math>\beta_i</math> = the coefficient for characteristic i from the waiting list measure, according to <i>Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients</i>.</p>

Where...	Includes...
$S_{TX}(t) = S_{TX,0}(t)e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \dots + \alpha_q Y_q}$	<p><math>S_{TX}(t)</math> = the expected post-transplant survival probability at time t for an individual candidate.</p> <p><math>Y_i</math> = the value of the <math>j^{th}</math> characteristic for an individual candidate</p> <p><math>\alpha_j</math> = the coefficient for characteristic j from the post-transplant survival measure, according to <i>Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients.</i></p>
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	<p>WLAUC = the area under the waiting list survival probability curve during the next year.</p>
$S_{WL}(t) = S_{WL,0}(t)e^{\beta_1 X_1 + \beta_2 X_2 + \dots + \beta_p X_p}$	<p><math>S_{WL,0}(t)</math> = the baseline waiting list survival probability at time t, according to <i>Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability.</i></p> <p><math>S_{TX,0}(t)</math> = the baseline post-transplant survival probability at time t, according to <i>Table 10-12: Baseline Post-Transplant Survival (S<sub>TX</sub>(t)) Probability.</i></p> <p><math>S_{WL}(t)</math> = the expected waiting list survival probability at time t for an individual candidate</p> <p><math>X_i</math> = the value of the <math>i^{th}</math> characteristic for an individual candidate.</p>

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Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

**Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients**

For this covariate:	The following coefficient is used in the LAS calculation:
Age (year)	0.0281444188123287*age
Bilirubin (mg/dL) value with the most recent test date and time	0.15572123729572*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL  0 when bilirubin is 1.0 mg/dL or less
Body mass index (BMI) (kg/m <sup>2</sup> )	0.10744133677215*(20 – BMI) for BMI less than 20 kg/m <sup>2</sup>  0 if BMI is at least 20 kg/m <sup>2</sup>

For this covariate:	The following coefficient is used in the LAS calculation:
Ventilation status if candidate is hospitalized	1.57618530736936 if continuous mechanical ventilation needed  0 if no continuous mechanical ventilation needed
Creatinine (serum) (mg/dL) with the most recent test date and time	0.0996197163645* creatinine if candidate is at least 18 years old  0 if candidate is less than 18 years old
Diagnosis Group A	0
Diagnosis Group B	1.26319338239175
Diagnosis Group C	1.78024171092307
Diagnosis Group D	1.51440083414275
Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.40107198445555
Detailed Diagnosis: Pulmonary fibrosis, other specify cause (Diagnosis Group D only)	0.2088684500011
<u>Detailed Diagnosis: COVID-19: pulmonary fibrosis (Diagnosis Group D only)</u>	<u>0.2088684500011</u>
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.64590852776042
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	1.39885489102977
<u>Detailed Diagnosis: Sarcoidosis with PA mean pressure missing (Diagnosis Group A only)</u>	<u>1.39885489102977</u>
Functional Status	-0.59790409246653 if no assistance needed with activities of daily living  0 if some or total assistance needed with activities of daily living
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0340531822566417*O <sub>2</sub> for Diagnosis Group B  0.08232292818591*O <sub>2</sub> for Diagnosis Groups A, C, and D
PCO <sub>2</sub> (mm Hg): current	0.12639905519026*PCO <sub>2</sub> /10 if PCO <sub>2</sub> is at least 40 mm Hg
PCO <sub>2</sub> increase of at least 15%	0.15556911866376 if PCO <sub>2</sub> increase is at least 15%  0 if PCO <sub>2</sub> increase is less than 15%

For this covariate:	The following coefficient is used in the LAS calculation:
Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	<p><math>0.55767046368853 * (PA \text{ systolic} - 40) / 10</math> for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg</p> <p>0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less</p> <p><math>0.1230478043299 * PA \text{ systolic} / 10</math> for Diagnosis Groups B, C, and D</p>
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.	$-0.09937981549564 * \text{Six-minute-walk distance} / 100$

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Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

**Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients**

For this covariate:	The following is used in the LAS calculation:
Age (years)	<p><math>0.0208895939056676 * (age - 45)</math> if candidate is greater than 45 years old</p> <p>0 if candidate is 45 years old or younger</p>
Creatinine (serum) at transplant (mg/dL) with the most recent data and time	<p><math>0.25451764981323 * \text{creatinine}</math> if candidate is at least 18 years old</p> <p>0 if candidate is less than 18 years old</p>
Cardiac index (L/min/m <sup>2</sup> ) at rest, prior to any exercise	<p>0.1448727551614 if less than 2 L/min/m<sup>2</sup></p> <p>0 if at least 2 L/min/m<sup>2</sup></p>
Ventilation status if candidate is hospitalized	<p>0.33161555489537 if continuous mechanical ventilation needed</p> <p>0 if no continuous mechanical ventilation needed</p>
Diagnosis Group A	0
Diagnosis Group B	0.51341349576197
Diagnosis Group C	0.23187885123342
Diagnosis Group D	0.12527366545917



For this covariate:	The following is used in the LAS calculation:
Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.12048575705296
Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only)	-0.33402539276216
<u>Detailed diagnosis: Constrictive bronchiolitis (Diagnosis Group D only)</u>	<u>-0.33402539276216</u>
Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	0.43537371336129
Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.98051166673574
<u>Detailed diagnosis: Sarcoidosis with PA mean pressure missing (Diagnosis Group A only)</u>	<u>0.98051166673574</u>
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0100383613234584*O <sub>2</sub> for Diagnosis Group A  0.0093694370076423*O <sub>2</sub> for Diagnosis Groups B, C, and D
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.	0.0001943695814883*(1200-Six-minute-walk distance)  0 if six-minute-distance-walked is at least 1,200 feet

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See *Policy 10.5: Probability Data Used in the LAS Calculation* for Tables 10-11 and 10-12 that provide data used in the LAS calculation.

**10.1.F.i Lung Disease Diagnosis Groups**

The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.

**Group A**

A candidate is in Group A if the candidate has *any* of the following diagnoses:

- 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

- 105 • Obstructive lung disease
- 106 • Primary ciliary dyskinesia
- 107 • Sarcoidosis with either:
- 108     ○ mean pulmonary artery pressure of 30 mm Hg or less
- 109     ○ missing mean pulmonary artery pressure
- 110 • Tuberosclerosis
- 111 • Wegener's granuloma – bronchiectasis

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113 **Group B**

114 A candidate is in Group B if the candidate has any of the following diagnoses:

- 116 • Congenital malformation
- 117 • CREST – pulmonary hypertension
- 118 • Eisenmenger's syndrome: atrial septal defect (ASD)
- 119 • Eisenmenger's syndrome: multi-congenital anomalies
- 120 • Eisenmenger's syndrome: other specify
- 121 • Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- 122 • Eisenmenger's syndrome: ventricular septal defect (VSD)
- 123 • Portopulmonary hypertension
- 124 • ~~Primary p~~Pulmonary hypertension/pulmonary arterial hypertension
- 125 • Pulmonary capillary hemangiomatosis
- 126 • Pulmonary telangiectasia – pulmonary hypertension
- 127 • Pulmonary thromboembolic disease
- 128 • Pulmonary vascular disease
- 129 • Pulmonary veno-occlusive disease
- 130 • Pulmonic stenosis
- 131 • Right hypoplastic lung
- 132 • Scleroderma – pulmonary hypertension
- 133 • Secondary pulmonary hypertension
- 134 • Thromboembolic pulmonary hypertension

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136 **Group C**

137 A candidate is in Group C if the candidate has *any* of the following diagnoses:

- 138
- 139 • Common variable immune deficiency
- 140 • Cystic fibrosis
- 141 • Fibrocavitary lung disease
- 142 • Hypogammaglobulinemia
- 143 • Schwachman-Diamond syndrome

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145 **Group D**

146 A candidate is in Group D if the candidate has *any* of the following diagnoses:

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- 148 • ABCA3 transporter mutation
- 149 • Alveolar proteinosis
- 150 • Amyloidosis

- 151 • Acute respiratory distress syndrome or pneumonia
- 152 • Bronchioloalveolar carcinoma (BAC)
- 153 • Carcinoid tumorlets
- 154 • Chronic pneumonitis of infancy
- 155 • Constrictive bronchiolitis
- 156 • COVID-19: acute respiratory distress syndrome
- 157 • COVID-19: pulmonary fibrosis
- 158 • CREST – Restrictive
- 159 • Eosinophilic granuloma
- 160 • Fibrosing Mediastinitis
- 161 • Graft versus host disease (GVHD)
- 162 • Hermansky Pudlak syndrome
- 163 • Hypersensitivity pneumonitis
- 164 • Idiopathic interstitial pneumonia, with at least one or more of the following
- 165 disease entities:
- 166 ○ Acute interstitial pneumonia
- 167 ○ Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing
- 168 pneumonia (BOOP)
- 169 ○ Desquamative interstitial pneumonia
- 170 ○ Idiopathic pulmonary fibrosis (IPF)
- 171 ○ Nonspecific interstitial pneumonia
- 172 ○ Lymphocytic interstitial pneumonia (LIP)
- 173 ○ Respiratory bronchiolitis-associated interstitial lung disease
- 174 • Idiopathic pulmonary hemosiderosis
- 175 • Lung retransplant or graft failure: acute rejection
- 176 • Lung retransplant or graft failure: non-specific
- 177 • Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- 178 • Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- 179 • Lung retransplant or graft failure: obstructive
- 180 • Lung retransplant or graft failure: other specify
- 181 • Lung retransplant or graft failure: primary graft failure
- 182 • Lung retransplant or graft failure: restrictive
- 183 • Lupus
- 184 • Mixed connective tissue disease
- 185 • Obliterative bronchiolitis: non-retransplant
- 186 • Occupational lung disease: other specify
- 187 • Paraneoplastic pemphigus associated Castleman’s disease
- 188 • Polymyositis
- 189 • Pulmonary fibrosis: other specify cause
- 190 • Pulmonary hyalinizing granuloma
- 191 • Pulmonary lymphangiectasia (PL)
- 192 • Pulmonary telangiectasia – restrictive
- 193 • Rheumatoid disease
- 194 • Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- 195 • Scleroderma – restrictive
- 196 • ~~Secondary pulmonary fibrosis: (specify cause)~~

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- Silicosis
  - Sjogren's syndrome
  - Surfactant protein B ~~mutation~~ deficiency
  - Surfactant protein C ~~mutation~~ deficiency
  - Teratoma
  - Wegener's granuloma – restrictive

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