OPTN

Notice of OPTN Policy Changes

Refine Lung Data Fields

Sponsoring Committee:	**Lung Transplantation**
Policies Affected:	***10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old***
	10.1.F: The LAS Calculation
Public Comment:	***April 27, 2021 – May 27, 2021***
Executive Committee Approved:	**July 30, 2021**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Policy Changes

These policy changes clarify data entry and the impact of specific diagnoses for Lung Allocation Score (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. The creation of distinct date fields for the components of Body Mass Index (BMI) (height and weight) will address how to update values when not collected on the same date, to more seamless uploads from electronic medical records (EMR) through the use of application programming interfaces (API). The combination of two of the diagnosis options for candidates with pulmonary fibrosis ("secondary pulmonary fibrosis" and "pulmonary fibrosis: other") will reduce ambiguity in reported diagnoses.

For candidates with diagnoses of "COVID-19: pulmonary fibrosis" or "constrictive bronchiolitis," policy was not clear that specific diagnosis coefficients apply. The addition of 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.

Proposal History

The OPTN conducts an annual assessment on at least one organ group as part of continuous quality improvement efforts. During an assessment focused on lung allocation, several areas for clarification were identified. These policy changes focus on the most urgent changes that can improve API integration and fit in with the implementation of previously approved LAS updates. These changes went out during a special public comment to enable the changes to be incorporated into other pending LAS changes approved by the OPTN Board of Directors in December 2020.[1] Other areas for improved alignment were identified and assigned different priorities.

[1] *Updated Cohort for Calculation of the Lung Allocation Score (LAS)*. OPTN. https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf

Summary of Changes

These changes clarify data entry and the impact of specific diagnoses in the LAS as they relate to the changes pending fall 2021 implementation. These changes are impacting the use of BMI, pulmonary fibrosis, and bronchiolitis in the LAS.

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 (Surfactant protein B deficiency, Surfactant protein C deficiency, Pulmonary hypertension/pulmonary arterial hypertension)
8. Removing language for missing or expired functional status value relating to the post-transplant measure and expired weight

Implementation

Members will not have to make any immediate adjustments for the changes in data collection associated with lung candidate listings, but will need to be aware of the different data collection patterns. Certain candidates may see a change to their LAS score as a result of these changes.

These changes will be programmed in UNet℠. Updates to the diagnoses that will now receive an LAS coefficient will be incorporated into programming.

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

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

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. 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 10-1* lists the normal and least beneficial values that will be substituted.

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
Height or weight to determine b~~B~~ody mass index (BMI)	Missing~~ or expired~~	100 kg/m^2
Weight to determine BMI	Expired	100 kg/m^2
Cardiac index	Missing	3.0 L/min/m^2

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
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 26.33 L/min in the post-transplant survival measure
PCO_2	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

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…
$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$	PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year. β_I = the coefficient for characteristic i from the waiting list measure, according to *Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients.*
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_i = the value of the j^{th} characteristic for an individual candidate $\propto_j$ = the coefficient for characteristic j from the post-transplant survival measure, according to *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients*.
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	WLAUC = the area under the waiting list survival probability curve during the next year.

Where…	Includes…
$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_p x_p}}$	$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to *Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability*. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to *Table 10-12: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability*. $S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate X_i = the value of the i^{th} characteristic for an individual candidate.

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^2)	0.10744133677215*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2
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

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Pulmonary fibrosis, other specify cause (Diagnosis Group D only)	0.2088684500011
Detailed Diagnosis: COVID-19: pulmonary fibrosis (Diagnosis Group D only)	0.2088684500011
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
Detailed Diagnosis: Sarcoidosis with PA mean pressure missing (Diagnosis Group A only)	1.39885489102977
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_2 for Diagnosis Group B 0.08232292818591*O_2 for Diagnosis Groups A, C, and D
PCO_2 (mm Hg): current	0.12639905519026*PCO_2/10 if PCO_2 is at least 40 mm Hg
PCO_2 increase of at least 15%	0.15556911866376 if PCO_2 increase is at least 15% 0 if PCO_2 increase is less than 15%
Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.55767046368853*(PA systolic – 40)/10 for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg 0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less 0.1230478043299*PA systolic/10 for Diagnosis Groups B, C, and D

For this covariate:	The following coefficient is used in the LAS calculation:
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*Six-minute-walk distance/100

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)	0.0208895939056676*(age–45) if candidate is greater than 45 years old 0 if candidate is 45 years old or younger
Creatinine (serum) at transplant (mg/dL) with the most recent date and time	0.25451764981323*creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
Cardiac index (L/min/m^2) at rest, prior to any exercise	0.1448727551614 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
Ventilation status if candidate is hospitalized	0.33161555489537 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
Diagnosis Group A	0
Diagnosis Group B	0.51341349576197
Diagnosis Group C	0.23187885123342
Diagnosis Group D	0.12527366545917
Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.12048575705296
Detailed diagnosis: Obliterative bronchiolitis: not-retransplant (Diagnosis Group D only)	-0.33402539276216
Detailed diagnosis: Constrictive bronchiolitis (Diagnosis Group D only)	-0.33402539276216
Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	0.43537371336129

For this covariate:	The following is used in the LAS calculation:
Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.98051166673574
Detailed diagnosis: Sarcoidosis with PA mean pressure missing (Diagnosis Group A only)	0.98051166673574
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0100383613234584*O_2 for Diagnosis Group A 0.0093694370076423*O_2 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

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
- Obstructive lung disease
- Primary ciliary dyskinesia
- Sarcoidosis with either:
    - mean pulmonary artery pressure of 30 mm Hg or less
    - missing mean pulmonary artery pressure
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B

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

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- 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 p~~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

Group C

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

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D

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

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- COVID-19: acute respiratory distress syndrome
- COVID-19: pulmonary fibrosis
- CREST – Restrictive
- Eosinophilic granuloma

- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with at least 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 (IPF)
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia (LIP)
  - 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 lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure ~~higher~~greater than 30 mm Hg
- Scleroderma – restrictive
- ~~Secondary pulmonary fibrosis: (specify cause)~~
- Silicosis
- Sjogren's syndrome
- Surfactant protein B ~~mutation~~ deficiency
- Surfactant protein C ~~mutation~~ deficiency
- Teratoma
- Wegener's granuloma – restrictive