OPTN

Briefing to the OPTN Board of Directors on

Refine Lung Data Fields

OPTN Lung Transplantation Committee

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Refine Lung Data Fields

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

Executive Summary

As part of continuing improvement efforts to improve the organ allocation system, staff conduct assessments of allocation policies and how data is collected and used for allocation in UNet[SM]. During the assessment 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) approved at the December 2020 OPTN Board of Directors Meeting. The previously approved proposal, "*Updated Cohort for Calculation of the Lung Allocation Score (LAS),*"[1] is planned for implementation in the fall of 2021. This proposal focuses on the most urgent changes that can improve the application programming interface (API) integration if implemented at the same time as the 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 clarify which specific sub-diagnoses receive coefficient adjustments in calculating LAS.

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[1] 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 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. This proposal focuses on the most urgent changes that can improve API integration (allowing seamless data uploads) and fit in with the implementation of previously approved LAS updates. These proposed changes were put out for a special public comment because, if approved, all needed LAS changes will be able to be programmed in conjunction with the changes to the LAS that were approved at the December 2020 Board meeting. 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 of lungs.

The proposed 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.[2]

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 how to update values when 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 reported diagnoses.

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

Public Comment Sentiment

This proposal was issued for special public comment from April 27, 2021, to May 27, 2021. The feedback is described below.

Sentiment is collected along a 5-point Likert scale from strongly oppose to strongly support (1-5) during public comment. All public comment sentiment from the community was supportive of this proposal. Below is a graphic that illustrates the sentiment received through public comment.

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[2] 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*.

Figure 1 shows the sentiment received during the special public comment period.

Figure 1: Special Public Comment Sentiment
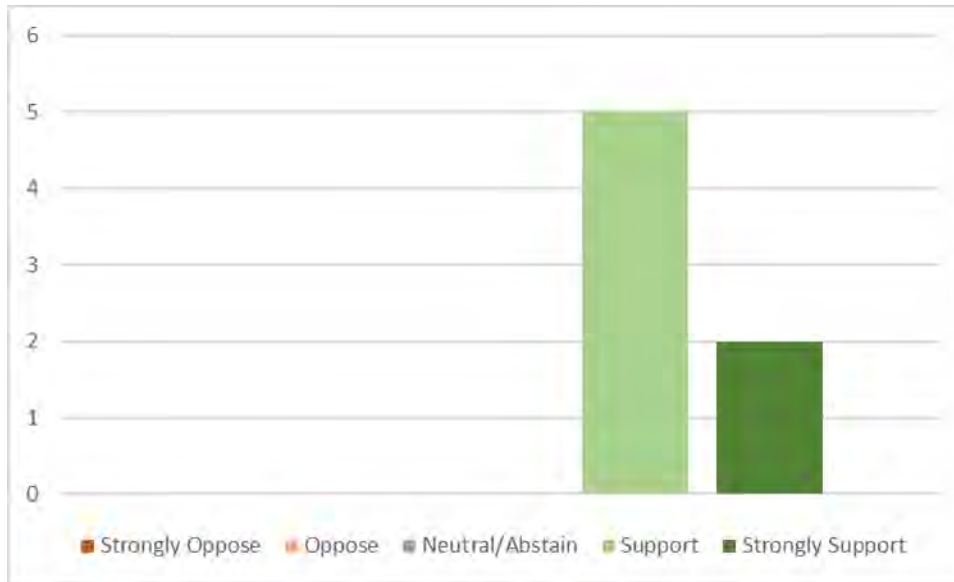
Proposal for Board Consideration

The Lung Transplantation Committee (Committee) proposes: [3]

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
8. Removing language for missing or expired functional status value relating to the post-transplant measure and expired weight

BMI

BMI is used in the LAS calculation and is collected in Waitlist℠ 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

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

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: LAS Values 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. For those candidates whose height may change within a 6-month period (e.g. pediatric candidates) the ability to enter updated values remains and will 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℠ related to pulmonary fibrosis:

1. "Pulmonary fibrosis: idiopathic pulmonary fibrosis (IPF)"
2. "Pulmonary fibrosis: other specify cause"
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 can 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."[4] 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. Combining these diagnoses into "pulmonary fibrosis: other specify cause" will improve equity among candidates by ensuring these candidates receive the same diagnosis coefficient.

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:

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[4] 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.

Pulmonary fibrosis" receive the detailed diagnosis coefficient adjustment to LAS for waiting list mortality. These changes will make a distinction between "idiopathic pulmonary fibrosis," which only receives the Group D coefficient adjustment, and all other pulmonary fibrosis diagnoses which would receive both the detailed diagnosis pulmonary fibrosis and Group D adjustments. All pulmonary fibrosis diagnoses will remain 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.[5] 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.[6] However, policy only lists the adjustment for "obliterative bronchiolitis" (see *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients*). This change will make it clearer that the coefficient adjustment applies for the post-transplant survival calculation to all candidates registered with either "obliterative bronchiolitis" or "constrictive bronchiolitis."[7][8] 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 whether candidates with sarcoidosis will be placed in Diagnosis Group A or D.[9] 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 will 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. As of June 2021, 30 of 1065 lung or heart/lung candidates were missing a value for PA. 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℠ and Transplant Information Electronic Data Interchange® (TIEDI). The Committee proposes changing the labels for three diagnoses to align with more current terminology, which is already being used in the system.

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[5] 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*.

[6] OPTN Briefing Paper, *Proposal to Revise the Lung Allocation Score (LAS) System*. 2012.

[7] 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 will be implemented at the same time as this removal, and therefore there is no need to align any wait list mortality adjustment.

[8] As of June 2021, there were 8 candidates using the obliterative (non-retransplant) bronchiolitis diagnosis and 0 candidates using the constrictive bronchiolitis diagnosis.

[9] 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.

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 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 proposal revises allocation policies for deceased donor lungs through several adjustments to fields that affect the calculation of the LAS.

This proposal 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 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.

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:

- **Is based on sound medical judgment[10]:** 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.
- **Seeks to achieve the best use of donated organs[11]:** 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".
- **Is designed to avoid futile transplants[12]:** 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

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[10] 42 CFR §121.8(a)(1).
[11] 42 CFR §121.8(a)(2).
[12] 42 CFR §121.8(a)(5).

survival for candidates with "constrictive bronchiolitis" and sarcoidosis with modeled post-transplant survival expectations.

- **Is designed to…promote patient access to transplantation[13] 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 align non-idiopathic pulmonary fibrosis, whether it is reported as "secondary pulmonary fibrosis" or "pulmonary fibrosis: other").

This proposal preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient, and it is specific to an organ type, in this case, lungs.

Although the outlined 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[14]
- Promotes the efficient management of organ placement[15]
- Is not based on the candidate's place of residence or place of listing[16]

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[17] The changes to BMI collection dates, obliterative and constrictive 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.[18] However, the anticipated changes in any candidate's LAS as a result of the coefficient changes is small and the Committee chose not to recommend a transition period, but rather to apply the new coefficient for these candidates immediately upon implementation.

Alignment with OPTN Strategic Plan[19]

Improve equity in access to transplants:
This proposal intends to improve equity in access to transplants for candidates by clarifying data entry and the impact of specific diagnoses for the LAS which ensures that similarly situated candidates are given equitable opportunities to receive an organ offer.

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[13] Ibid.
[14] Ibid.
[15] Ibid.
[16] 42 CFR §121.8(a)(8).
[17] C.F.R. § 121.8(d).
[18] 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."
[19] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategiplan/

Implementation Considerations

Member and OPTN Operations

Changes to Waitlist℠ 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.[20] 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.[21]

Changes will also include a correction to *Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS* by removing reference to a missing value or expired value for functional status for the post-transplant survival measure since there is no coefficient for post-transplant survival as part of the *Updated Cohort for Calculation of the Lung Allocation Score (LAS).*

Operations affecting Transplant Hospitals

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

This proposal would require the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the proposed data collection changes will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Operations affecting the OPTN

This proposal will require updates to the current LAS submission form and programming.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of Histocompatibility Laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of Organ Procurement Organizations.

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[20] *OPTN Policy Notice, "Updated Cohort for Calculation of the Lung Allocation Score (LAS)",* https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf
[21] There is no corresponding date field on these forms for adult lung recipients.

Briefing Paper

Projected Fiscal Impact

Projected Impact on 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.

Projected Impact on the OPTN

A very small IT implementation effort, estimated at 80 hours, will include the addition of new data collection fields to allow separate data collection on height and weight. This change will affect Waitlist[SM] and TIEDI®. No ongoing resource requirements are anticipated.

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on OPOs.

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."[22]

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[SM] 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."[23]

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

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.

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[22] 42 CFR §121.8(a)(7).
[23] 42 CFR §121.8(a)(6).
[24] https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf.

Conclusion

This proposal will clarify data entry and the impact of specific diagnoses for LAS. Creating distinct date fields for the components of BMI (height and weight) will provide clarity 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. The additional clarification for how a candidate's mean PA pressure is treated when the value is missing will help ensure candidates understand what is being used to calculate their LAS and updating the names for the three diagnoses listed will align the labels of the diagnoses codes between what is in policy and UNet[SM]. These changes will provide refined clarity and consistency for LAS.

Policy Language

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

42	performs a heart catheterization test on the candidate during the six month interval, then it
43	must report the data to the OPTN.
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45	If values for certain covariates are missing, expired, or below the threshold as defined by *Table*
46	*10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the
47	candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least
48	beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal
49	and least beneficial values that will be substituted.
50	
51	**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 b</u>~~B~~ody mass index (BMI)	Missing ~~or expired~~	100 kg/m^2
<u>Weight to determine BMI</u>	<u>Expired</u>	<u>100 kg/m^2</u>
Cardiac index	Missing	3.0 L/min/m^2
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~~

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
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 jth characteristic for an individual candidate α_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.
$$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$$	$S_{WL,0}(t)$ = 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 ith characteristic for an individual candidate.

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

Briefing Paper

For this covariate:	The following coefficient is used in the LAS calculation:
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
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.	$-0.09937981549564*Six\text{-}minute\text{-}walk\ distance/100$

80
81   *Table 10-4* lists the covariates and corresponding coefficients in the waiting list and post-
82   transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific
83   information on each diagnosis group.
84
85   **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 data 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

For this covariate:	The following is used in the LAS calculation:
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: no±n-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
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.	$0.0001943695814883 * (1200 - \text{Six-minute-walk distance})$ 0 if six-minute-distance-walked is at least 1,200 feet

86
87   See *Policy 10.5: Probability Data Used in the LAS Calculation* for *Tables 10-11* and *10-12* that
88   provide data used in the LAS calculation.
89
90   **10.1.F.i   Lung Disease Diagnosis Groups**
91   The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.
92
93   ***Group A***
94   A candidate is in Group A if the candidate has *any* of the following diagnoses:
95
96   • Allergic bronchopulmonary aspergillosis

97	• Alpha-1 antitrypsin deficiency
98	• Bronchiectasis
99	• Bronchopulmonary dysplasia
100	• Chronic obstructive pulmonary disease/emphysema
101	• Ehlers-Danlos syndrome
102	• Granulomatous lung disease
103	• Inhalation burns/trauma
104	• Kartagener's syndrome
105	• Lymphangioleiomyomatosis
106	• Obstructive lung disease
107	• Primary ciliary dyskinesia
108	• Sarcoidosis with <u>either:</u>
109	o mean pulmonary artery pressure of 30 mm Hg or less
110	o <u>missing mean pulmonary artery pressure</u>
111	• Tuberous sclerosis
112	• Wegener's granuloma – bronchiectasis
113	
114	**Group B**
115	A candidate is in Group B if the candidate has any of the following diagnoses:
116	
117	• Congenital malformation
118	• CREST – pulmonary hypertension
119	• Eisenmenger's syndrome: atrial septal defect (ASD)
120	• Eisenmenger's syndrome: multi-congenital anomalies
121	• Eisenmenger's syndrome: other specify
122	• Eisenmenger's syndrome: patent ductus arteriosus (PDA)
123	• Eisenmenger's syndrome: ventricular septal defect (VSD)
124	• Portopulmonary hypertension
125	• ~~Primary p~~<u>P</u>ulmonary hypertension/pulmonary arterial hypertension
126	• Pulmonary capillary hemangiomatosis
127	• Pulmonary telangiectasia – pulmonary hypertension
128	• Pulmonary thromboembolic disease
129	• Pulmonary vascular disease
130	• Pulmonary veno-occlusive disease
131	• Pulmonic stenosis
132	• Right hypoplastic lung
133	• Scleroderma – pulmonary hypertension
134	• Secondary pulmonary hypertension
135	• Thromboembolic pulmonary hypertension
136	
137	**Group C**
138	A candidate is in Group C if the candidate has *any* of the following diagnoses:
139	
140	• Common variable immune deficiency
141	• Cystic fibrosis
142	• Fibrocavitary lung disease

143   •   Hypogammaglobulinemia

144   •   Schwachman-Diamond syndrome

145

146   **Group D**

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

148

149   •   ABCA3 transporter mutation

150   •   Alveolar proteinosis

151   •   Amyloidosis

152   •   Acute respiratory distress syndrome or pneumonia

153   •   Bronchioloalveolar carcinoma (BAC)

154   •   Carcinoid tumorlets

155   •   Chronic pneumonitis of infancy

156   •   Constrictive bronchiolitis

157   •   COVID-19: acute respiratory distress syndrome

158   •   COVID-19: pulmonary fibrosis

159   •   CREST – Restrictive

160   •   Eosinophilic granuloma

161   •   Fibrosing Mediastinitis

162   •   Graft versus host disease (GVHD)

163   •   Hermansky Pudlak syndrome

164   •   Hypersensitivity pneumonitis

165   •   Idiopathic interstitial pneumonia, with at least one or more of the following

166   disease entities:

167   ○   Acute interstitial pneumonia

168   ○   Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing

169   pneumonia (BOOP)

170   ○   Desquamative interstitial pneumonia

171   ○   Idiopathic pulmonary fibrosis (IPF)

172   ○   Nonspecific interstitial pneumonia

173   ○   Lymphocytic interstitial pneumonia (LIP)

174   ○   Respiratory bronchiolitis-associated interstitial lung disease

175   •   Idiopathic pulmonary hemosiderosis

176   •   Lung retransplant or graft failure: acute rejection

177   •   Lung retransplant or graft failure: non-specific

178   •   Lung retransplant or graft failure: obliterative bronchiolitis-obstructive

179   •   Lung retransplant or graft failure: obliterative bronchiolitis-restrictive

180   •   Lung retransplant or graft failure: obstructive

181   •   Lung retransplant or graft failure: other specify

182   •   Lung retransplant or graft failure: primary graft failure

183   •   Lung retransplant or graft failure: restrictive

184   •   Lupus

185   •   Mixed connective tissue disease

186   •   Obliterative bronchiolitis: non-retransplant

187   •   Occupational lung disease: other specify

188   •   Paraneoplastic pemphigus associated Castleman's disease

189	•	Polymyositis
190	•	Pulmonary fibrosis: other specify cause
191	•	Pulmonary hyalinizing granuloma
192	•	Pulmonary lymphangiectasia (PL)
193	•	Pulmonary telangiectasia – restrictive
194	•	Rheumatoid disease
195	•	Sarcoidosis with mean pulmonary artery pressure ~~higher~~ greater than 30 mm Hg
196	•	Scleroderma – restrictive
197	•	~~Secondary pulmonary fibrosis: (specify cause)~~
198	•	Silicosis
199	•	Sjogren's syndrome
200	•	Surfactant protein B ~~mutation~~ deficiency
201	•	Surfactant protein C ~~mutation~~ deficiency
202	•	Teratoma
203	•	Wegener's granuloma – restrictive

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