

**OPTN Executive Committee
Meeting Summary
July 30, 2021
Conference Call**

**Matthew Cooper, MD, Chair
Jerry McCauley, MD, Chair**

Introduction

The Executive Committee met via Citrix GoToMeeting teleconference on 07/30/2021 to discuss the following agenda items:

1. COVID-19 Policy Data Review
2. OPTN Charter Revision Project
3. Refine Lung Data Fields
4. Summer 2021 Public Comment Proposals and New Projects

The following is a summary of the Committee's discussions.

1. COVID-19 Policy Data Review

Dr. Cooper welcomed the Committee to the meeting and introduced Laura Cartwright to provide an update on the COVID-19 emergency policy data. Dr. Cartwright reminded the group of the status of all COVID-19 related policies. Policy 3, modify wait times for non-dialysis kidney candidates, is used in roughly one third of listings. The proportion of total waiting time modification forms submitted to the UNOS Organ Center has been decreasing in volume. Policy 1, updating candidate data during COVID-19, had very low usage prior to repeal. For Policy 2, relax data submission requirements for follow-up forms, the vast majority of forms have been submitted. The median number of forms by center is zero. Three centers represent 78% of all expected TRF forms, and UNOS is following up with those centers directly.

Sarah Booker presented one-month post implementation monitoring for Lower Respiratory SARS-CoV-2 Testing for Lung Donors. This was an emergency policy implemented on May 27, 2021, requiring lower respiratory testing (LRT) for all potential deceased lung donors. Since implementation, there have been 252 deceased lung donors, and 100% of donors received LRT. Over 90% of donors had testing results reported in DonorNet before the day of transplant. 53 OPOs have recovered lung donors post implementation. All recovered lungs had LRT performed, even if the lungs were not transplanted. Since implementation, 7 donors had positive LRT results. All 7 had at least 1 upper respiratory test that was negative. Lungs were not recovered from these donors. Overall, there is high compliance with the LRT requirement.

Dr. Cooper asked if any OPO representatives have faced unique challenges regarding this policy. One OPO representative commented that her OPO has not faced any challenges with this policy, and that compliance with this policy is very important.

2. OPTN Charter Revision Project

Dr. Cooper introduced Liz Callahan Robbins, Associate General Counsel, to present on the OPTN Charter Revision project. Ms. Callahan Robbins explained that the per OPTN contract task 3.2.2, the OPTN contractor should coordinate the Board's review of the OPTN Charter. This project will include review of

membership categories. Ms. Callahan Robbins explained the purpose of the charter, noting that the OPTN's charter has minimal legal significance. The last substantial charter revision took place in June 2004. The potential revisions include: minimizing duplication/ensuring consistency with NOTA, the Final Rule, the Charter, and Bylaws, removing references to UNOS and clarifying the relationship between OPTN and UNOS, and confirming *Purpose* and *Membership* categories. Mrs. Callahan reviewed the project plan and timeline. There were no questions or comments from the EC.

3. Refine Lung Data Fields

Dr. Erika Lease, Chair of the OPTN Lung Committee, presented the Refine Lung Data Fields proposal. Dr. Lease explained that the proposal is an important part of the transition to continuous distribution. The proposal clarifies data entry, ensures that data are reported consistently, promotes equity among candidates, and provides additional clarity in the policy language. During the special public comment period, the proposal was broadly supported by the community and stakeholder organizations. Some candidates may see a change to their LAS score as a result of these changes. This is a small project, and if approved, the changes will be programmed in to UNet. There were no questions from the Committee.

By a vote of 100% yes, 0 no, and 0 abstentions, it was

RESOLVED, that the changes to Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old and Policy 10.1.F: The LAS Calculation , as set forth in the materials distributed to the Executive Committee on July 23, 2021, are hereby approved, pending notice and implementation.

See **Exhibit A** for additional information on this proposal. Dr. Cooper thanked Dr. Lease for her presentation.

4. Summer 2021 Public Comment Proposals and New Projects

Dr. Cooper introduced Dr. Nicole Turgeon, Chair of the Policy Oversight Committee (POC), to present summer 2021 public comment proposals and 3 new projects. In May 2021, the POC received presentations on the public comment items and no significant concerns were identified. In July, the POC reviewed each item in-depth, they discussed the items as a group, identified any major areas of concern, and voted to recommend proposals to the Executive Committee. Dr. Turgeon explained that the POC identified challenges with two proposals:

- **Guidance for Data Collection Regarding Classification of Citizenship Status (Ad-Hoc International Relations Committee):** Dr. Turgeon explained that in February 2021 the POC approved work on the guidance document, with the conditions that the AHIRC refine the scope of the proposal and ensure inclusion of relevant stakeholders. In March 2021, the Executive Committee (EC) approved this item as a new project. In May 2021, the POC reviewed a high-level synopsis of this proposal. On July 26, the POC voted to not recommend this proposal for summer 2021 Public Comment. The POC was concerned with the focus on citizenship status instead of residency status. The original goal of the data collection was to evaluate transplant tourism and appropriate follow up for living donors and recipients, and the POC was concerned with asking members to verify citizenship status with donor families and transplant candidates who are non-citizens. Additionally, the POC noted that there were conflicting statements in the guidance document, stating that it is not within the scope of the OPTN to discern citizenship status, but then listing acceptable documentation to confirm citizenship status. The document also used the terms "residency" and "citizenship status" interchangeably, which could cause confusion.

After proving this feedback to the AHIRC, the AHIRC added an opening paragraph to clarify the term “citizenship status” refers to the OPTN data collection element “citizenship status”, they removed a sentence with a typo, and deleted a paragraph that recommended types of acceptable documentation for collecting citizenship status. Mr. Barry Friedman, Chair of the AHIRC, joined the EC to share additional information. Mr. Friedman clarified that this item is a guidance document, and does not include any changes to policy. The AHIRC made the changes following the concerns from the POC, and the Committee voted to approve the revised document. A member of the EC asked Mr. Friedman to explain the original goal of the proposal, and Mr. Friedman explained that a study showed that transplant centers do not have a standardized way to obtain and collect citizenship status. The AHIRC felt this data should be as accurate and consistent as possible, and hopes that this guidance document will provide the OPTN with better data. It will also provide transplant centers with better data about international transplant patients. A member of the EC asked if this proposal has been reviewed by legal counsel. Dr. Turgeon explained that the proposal was reviewed by legal counsel. Mr. Brian Shepard noted that the OPTN cannot distinguish between candidates based on non-medical criteria, so while the OPTN can collect data to better understand non-resident transplant, it would take an act of Congress to decide that there is a difference between resident and non-resident patients. The OPTN will not treat candidates differently for non-medical reasons. Another member of the EC asked if the AHIRC has considered any potential negative impacts to patients. Mr. Friedman explained that this should be handled proactively instead of reactively. A member of the EC asked if information on deceased donors was included in the guidance document. Mr. Friedman shared that the AHIRC determined this was outside of the scope of this document. Based on the revisions completed by the AHIRC, the POC felt comfortable recommending the guidance document for approval.

- Ethical Considerations of Continuous Distribution in Organ Allocation (Ethics Committee): Dr. Turgeon explained that the POC recommended the Ethical Considerations of Continuous Distribution in Organ Allocation white paper with no concerns. The Ethics Committee updated the white paper following POC review to address feedback received from HRSA. Mr. Christopher McLaughlin said that HRSA has no additional comments about the white paper.

Dr. Turgeon shared the strategic plan alignment for the remaining public comment proposals for summer 2021. The EC had no further questions or comments. The EC voted to approve the release of the projects for summer 2021 public comment by a vote of 100% yes, 0 no, and 0 abstentions.

Dr. Turgeon introduced three new projects:

- Redefining Provisional Yes and the Approach to Organ Offers (OSC): This project aligns with the strategic policy priority of efficiency. The OSC is working to redefine provisional yes, limit the amount of organ offers, modify organ offer time limits with system enforcement, and modify organ offer notifications.
- Mandatory Offer Filters (OSC): This project mandates the use of offer filters based on identified criteria in policy, which would allow transplant programs to screen off donor offers they are less likely to accept through custom-designed, multi-criteria filters. One member of the EC noted that this project came from the Systems Performance Committee. One EC member asked how the OPTN plans to enforce mandatory filters. Dr. Turgeon noted that this proposal will seek to answer that question and determine how the OPTN can enforce mandatory filters. Another member of the EC noted that this project should focus on what makes centers say “yes”, as well

as what influences centers to say “no”, commenting that there is important work to be done on managing notifications.

- Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing (DTAC): This project will modify the timing requirement of pre-transplant HIV, HBV, and HCV testing for certain pediatric candidates. This project will increase patient safety for pediatric candidates where the risk of overdrawing blood volume for testing directly prior to transplant is greater.

Dr. Turgeon showed the strategic plan and strategic policy priority alignment for the new projects. Dr. Turgeon reviewed the resources required for each new project, which is one of the many factors that the POC considers when developing and reviewing new projects. Dr. Turgeon explained the implementation hours for each Board cycle, noting that the OPTN was over budget for three recent cycles. The POC is continuing to monitor the budget for upcoming Board cycles. One EC member asked how the OPTN plans to budget for unexpected projects. Dr. Turgeon explained that the OPTN has to be flexible, and that the POC coordinates closely with UNOS staff. There were no further questions. The EC approved the new projects with a vote of 100% yes, 0 no, and 0 abstentions.

Upcoming Meetings

- September 22, 2021
- October, 2021
- December 2021

Attendance

- **Committee Members**
 - Matt Cooper
 - Jerry McCauley
 - Lisa Stocks
 - Mindy Dison
 - Brad Kornfeld
 - Richard Formica
 - Patrick Healey
 - Stacey Lerret
 - William Hildebrand
 - Brian Shepard, OPTN Executive Director (Ex-Officio, Non-Voting)
- **HRSA Representatives**
 - Chris McLaughlin
 - Frank Holloman
 - Shannon Dunne
- **SRTR Staff**
 - Ajay Israni
- **UNOS Staff**
 - Laura Cartwright
 - Susie Sprinson
 - Carrie Caumont
 - Sarah Booker
- **Other Attendees**
 - Nicole Turgeon
 - Barry Friedman
 - Erika Lease

Briefing to the OPTN Board of Directors on

Refine Lung Data Fields

OPTN Lung Transplantation Committee

Exhibit A

*Prepared by: Krissy Laurie, MS
UNOS Policy and Community Relations Department*

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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 UNetSM. 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.

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

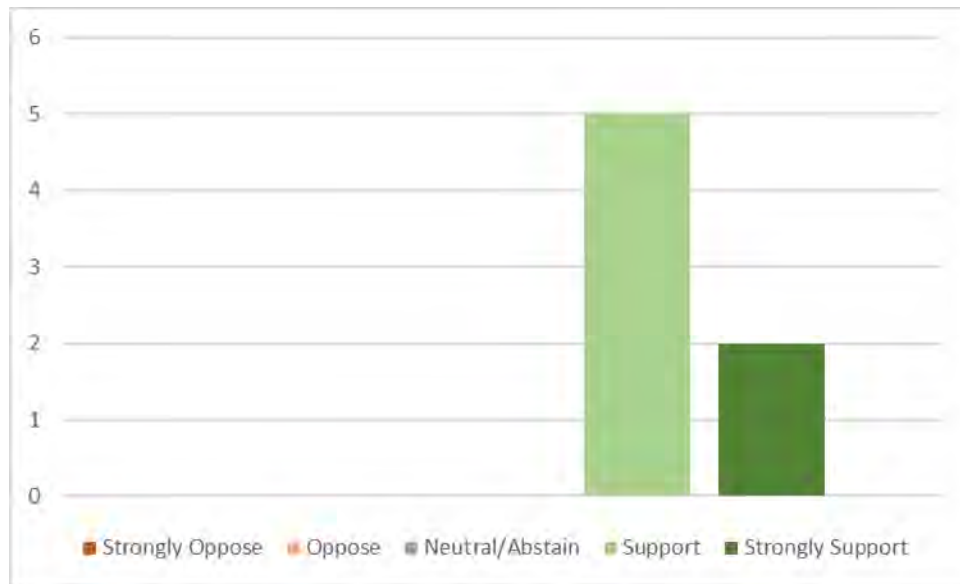
This proposal was issued for special public comment from April 27, 2021, to May 27, 2021. The feedback is described below.

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.

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 WaitlistSM 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

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 WaitlistSM 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:

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.”⁷⁸ 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 WaitlistSM 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.

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 judgment¹⁰:** 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 organs¹¹:** 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 transplants¹²:** 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

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 transplantation¹³** 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 organs¹⁴
- Promotes the efficient management of organ placement¹⁵
- Is not based on the candidate’s place of residence or place of listing¹⁶

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 Plan¹⁹

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.

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 WaitlistSM 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.

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.

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 WaitlistSM 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 UNetSM 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.

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 UNetSM. These changes will provide refined clarity and consistency for LAS.

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

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.

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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 body 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
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

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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:

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

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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>β_i = 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>
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \dots + \alpha_q Y_q}}$	<p>$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate.</p> <p>Y_i = the value of the j^{th} characteristic for an individual candidate</p> <p>α_j = 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>$S_{WL,0}(t)$ = 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>$S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to <i>Table 10-12: Baseline Post-Transplant Survival (S_{TX}(t)) Probability</i>.</p> <p>$S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate</p> <p>X_i = the value of the i^{th} 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)	$0.0281444188123287 * \text{age}$
Bilirubin (mg/dL) value with the most recent test date and time	$0.15572123729572 * (\text{bilirubin} - 1)$ 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)	$0.10744133677215 * (20 - \text{BMI})$ 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	$0.0996197163645 * \text{creatinine}$ 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

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-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)	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: 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
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

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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

- 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 either:
- 109 ○ mean pulmonary artery pressure of 30 mm Hg or less
- 110 ○ missing mean pulmonary artery pressure
- 111 • Tuberos sclerosis
- 112 • Wegener's granuloma – bronchiectasis

Group B

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

- 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~~Pulmonary 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

Group C

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

- 140 • Common variable immune deficiency
- 141 • Cystic fibrosis
- 142 • Fibrocavitary lung disease

- 143 • Hypogammaglobulinemia
- 144 • Schwachman-Diamond syndrome

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146 **Group D**

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

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- 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

- 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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