OPTN

Public Comment Proposal

Incorporating COVID-19 Related Organ Failure In Candidate Listings

OPTN Lung Transplantation Committee

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Incorporating COVID-19 Related Organ Failure In Candidate Listings

Affected Policies: *10.1.F.i Lung Disease Diagnosis Groups*
Sponsoring Committee: *Lung Transplantation*
Public Comment Period: *August 31, 2020 – October 1, 2020*

Executive Summary

Lung transplantation has emerged as a treatment option for some patients with severe lung damage resulting from COVID-19. The OPTN does not have a method for identifying candidate listings for COVID-19 related organ failure. Although at least three such patients are known to have been transplanted in the United States, it is currently unknown whether other candidates have been listed or transplanted as a result of lung disease caused by COVID-19.

This proposed change would establish standard diagnoses for listing lung candidates due to damage caused by COVID-19. This will allow identification of trends in listing candidates for COVID-19, and potentially even more accurate inclusion in future updates to the Lung Allocation Score (LAS) calculation.

Reports of injury to other organs from COVID-19 have emerged as well, including heart, kidney and liver.[1] The OPTN Lung Transplantation Committee (Lung Committee) is seeking feedback on whether there are other diagnoses caused by COVID-19 infection that would lead to listing a patient for lung transplant, whether candidates for other organ transplants are being listed due to COVID-19 related organ failure, and whether the OPTN should establish COVID-19 related diagnosis codes for other organs.

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[1] Qingxing Chen, Lili Xu, Yongbin Dai, Yunlong Ling, Jiahao Mao, Juying Qian, Wenqing Zhu, Wencheng Di, Junbo Ge, "Cardiovascular manifestations in severe and critical patients with COVID -19." *Clinical Cardiology,* 20 June 2020.

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Background

The World Health Organization has labeled COVID-19 as a pandemic[2], and the death toll has exceeded 154,000 in the United States alone.[3] In some candidates with severe cases of COVID-19, lasting damage to the lungs is being treated with lung transplantation. Three such transplants have been reported in the United States,[4] while at least six COVID-19 related lung transplant cases have been reported in China and one has been reported in Austria.[5]

Northwestern Medical Center performed two double lung transplants on patients whose lungs were damaged by COVID-19.[6] The University of Florida Health also performed a double lung transplant for a patient due to COVID-19.[7] According to news sources, other patients have been evaluated for lung transplant at Keck Hospital of the University of Southern California,[8] and other transplant centers have anecdotally reported evaluating similar candidates for listing for lung transplant.

There have not been similar reports of other organs transplanted to address organ failure from COVID-19, but there is emerging evidence that COVID-19 can cause lasting damage to other organs. In light of developing evidence that COVID-19 causes heart[9] and kidney[10] damage, there are concerns that it may lead to irreversible damage as there are more cases and more time lapses.[11] There is also evidence that liver damage is common in COVID-19 patients, although it is unclear whether COVID-19 is the direct cause.[12]

Purpose

This proposed change will allow lung candidates listed as a result of COVID-19 related disease to be identified to support future calculation of appropriate lung allocation scores (LAS), which is one factor used to sort candidates on the match. It will also permit the OPTN to analyze patterns in candidates

[2] World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*, March 11, 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.
[3] Centers for Disease Control and Prevention, *Daily Updates of Totals by Week and State*, August 18, 2020, https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.
[4] D. Hagmajer, *UF Health surgeons perform historic double-lung transplant on COVID-19 survivor*, July 30, 2020. https://ufhealth.org/news/2020/uf-health-surgeons-perform-historic-double-lung-transplant-covid-19-survivor.
[5] Crystal Phend, Transplant for COVID-Ravaged Lungs: Caution Ahead, Medpage Today, June 17, 2020, https://www.medpagetoday.com/infectiousdisease/covid19/87136.
[6] Northwestern Memorial Hospital, *Meet the Two COVID-19 Patients Who Received Double-Lung Transplants at Northwestern Medicine*, July 30, 2020. https://www.nm.org/about-us/northwestern-medicine-newsroom/press-releases/2020/meet-the-two-covid19-double-lung-transplant-patients.
[7] D. Hagmajer, *UF Health surgeons perform historic double-lung transplant on COVID-19 survivor*, July 3o, 2020. https://ufhealth.org/news/2020/uf-health-surgeons-perform-historic-double-lung-transplant-covid-19-survivor.
[8] Veronica Miracle. "Palm Springs nurse in need of lung transplant after monthslong battle with COVID-19." *ABC 7 News*, August 9, 2020, https://abc7news.com/nurse-covid-lung-transplant-palm-springs-patient-providence-saint-johns-health-center/6362814/;
Sharon Song, "COVID-19 leaves college student and teen brother only survivors in household." *WIFR*, July 30, 2020, https://www.wifr.com/2020/07/30/covid-19-leaves-college-student-and-teen-brother-only-survivors-in-household/.
[9] Yancy CW, Fonarow GC. "Coronavirus Disease 2019 (COVID-19) and the Heart—Is Heart Failure the Next Chapter?" *JAMA Cardiol*. Published online July 27, 2020. doi:10.1001/jamacardio.2020.3575.
[10] Jain Wu, Shu Song, Hong-Cui Cao and Lan-Juan Li, Liver diseases in COVID-19: Etiology, treatment and prognosis. *World journal of gastroenterology*, *26*(19), 2286–2293.
[11] Yancy CW, Fonarow GC. "Coronavirus Disease 2019 (COVID-19) and the Heart—Is Heart Failure the Next Chapter?" *JAMA Cardiol*. Published online July 27, 2020. doi:10.1001/jamacardio.2020.3575.
[12] Jain Wu, Shu Song, Hong-Cui Cao and Lan-Juan Li, Liver diseases in COVID-19: Etiology, treatment and prognosis. *World journal of gastroenterology*, *26*(19), 2286–2293.

listed because of organ damage from COVID-19. The ability to analyze data on this specific candidate population will allow the transplant system to more quickly identify trends and adapt as needed.

The Lung Committee submits the following proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs."[13] Furthermore, "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN...information regarding transplant candidates, transplant recipients, [and] donors of organs...."[14] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients"[15] and shall "...receive...such records and information electronically..."[16]

Overview of Proposal

The Lung Committee proposes adding two new options to the diagnosis drop down menu in UNet℠ for lung candidates. The proposed diagnoses are "COVID-19: acute respiratory distress syndrome (ARDS)" and "COVID-19: pulmonary fibrosis," and would be added to LAS Group D in lung allocation policy. Capturing the information discretely for COVID-19 related ARDS and pulmonary fibrosis will allow the OPTN to evaluate the impact COVID-19 is having on lung transplant, and establish a data set for long term study of whether outcomes and mortality for COVID-related disease is different than non-COVID related disease.

The Lung Committee recognizes the value in collecting information consistently across organs, and is therefore also considering suggesting similar new options for the diagnosis fields for the other organs. Lung Committee leadership has consulted with other OPTN committees; the Lung Committee agreed adding an inquiry about diagnosis codes for other organs would be an appropriate addition to this lung proposal.

The Lung Committee would like feedback on:
- For lung, are there diagnoses other than ARDS and pulmonary fibrosis that would be caused by COVID-19 and require lung transplantation?
- Are candidates for other organs being listed due to COVID-19 related organ failure?
- Should the OPTN establish COVID-19 related diagnosis codes for other organs?

Lung

COVID-19 is primarily a respiratory illness. "The most frequent, serious manifestation of COVID-19 infection seems to be pneumonia... Although most patients will only experience mild symptoms of the disease, some patients will experience rapid progression of their symptoms... One study found that 17% of their patients developed Acute Respiratory Distress Syndrome (ARDS) and among these, 65% rapidly worsened and died from multiple organ failure."[17] There have been at least three double lung

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[13] 42 CFR §121.8(a).
[14] 42 CFR §121.11(b)(2).
[15] 42 CFR §121.11(a)(1)(ii).
[16] 42 CFR §121.11(a)(1)(iii).
[17] Zaim, S., Chong, J. H., Sankaranarayanan, V., & Harky, A. (2020). COVID-19 and Multiorgan Response. *Current problems in cardiology*, *45*(8), 100618. https://doi.org/10.1016/j.cpcardiol.2020.100618

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transplants, and more candidates placed on the waitlist as a result of ARDS or pneumonia from COVID-19.[18] The Lung Committee proposes including COVID-19 diagnosis options for lung candidates.

Heart

Cardiac injury is a relatively common complication in severely ill COVID-19 patients.[19] In an analysis from Wuhan, China, 23% of critically ill COVID-19 patients had cardiac injury. It is not possible to say with certainty whether any candidates have been listed or transplanted with a heart as a result of COVID-19, because no heart candidate listings have been publically reported and that information is not collected by the OPTN. Leaders from the Heart Transplantation Committee have stated that they expect heart candidates to be listed soon based on the type of heart damage they are observing in their medical practice. The Lung Committee is seeking feedback on whether COVID-19 diagnoses should be collected on heart candidates.

Kidney

COVID-19 causes acute kidney injury (AKI) in many severe cases of COVID-19, especially those where hospitalization is required.[20] In one analysis, about half of the patients admitted to the hospital as a result of COVID-19 had reached Kidney Disease Improving Global Outcomes (KDIGO) stage 1 AKI, and 14.3% of those required dialysis.[21] Of those that required dialysis, most required invasive mechanical ventilation, and the timing of the intubation and the diagnosis of AKI are highly correlated.

There have not been any reported kidney transplants to treat damage from COVID-19. This may be because of the high risk of death, and other complicating factors such as ventilator dependence once a patient needs renal replacement in the progression of COVID-19. Without collecting this specific information regarding the kidney diagnosis in UNet, it is difficult to be certain that no candidates have been listed as a result of COVID-19. The Kidney Transplantation Committee supports collecting similar diagnosis information when kidney candidates are registered. The Lung Committee is seeking additional feedback on whether COVID-19 diagnoses should be collected on kidney candidates.

Liver and Intestine

Early data appear to indicate that COVID-19 can affect the gastrointestinal tract and liver.[22] Liver damage has been reported in COVID-19 patients, proportionate to the severity of COVID-19. In the Wuhan study, 29% of severely ill COVID-19 patients had liver damage.[23]

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[18] Denise Grady, "A Covid Patient Goes Home After a Rare Double Lung Transplant", *The New York Times,* July 30, 2020. https://www.nytimes.com/2020/07/30/health/Covid-lung-transplant.html
[19] Dariya, B., & Nagaraju, G. P. (2020). Understanding novel COVID-19: Its impact on organ failure and risk assessment for diabetic and cancer patients. *Cytokine & growth factor reviews*, *53*, 43–52. https://doi.org/10.1016/j.cytogfr.2020.05.001
[20] Daniel Batlle, Maria Jose Soler, Matthew A. Sparks, Swapnil Hiremath, Andrew M. South, Paul A. Welling, Sundararaman. "Acute Kidney Injury in COVID-19: Emerging Evidence of a Distinct Pathophysiology." *JASN* Jul 2020, 31 (7) 1380-1383; DOI: 10.1681/ASN.2020040419
[21] Jamie S. Hirsch, Jia H. Ng, Daniel W. Ross, Purva Sharma, Hitesh H. Shah, Richard L. Barnett1 , Azzour D. Hazzan1 , Steven Fishbane and Kenar D. Jhaveri. "Acute kidney injury in patients hospitalized with COVID-19" *Kidney International* (2020) 98, 209–218.
[22] Yang, Lijing et al.. "Implications of gastrointestinal manifestations of COVID-19." https://www.thelancet.com/journals/langas/article/PIIS2468-1253(20)30132-1/fulltext. *The Lancet Gastroenterology & Hepatology*, Volume 5, Issue 7, 629 - 630
[23] Zaim, S., Chong, J. H., Sankaranarayanan, V., & Harky, A. (2020). COVID-19 and Multiorgan Response. *Current problems in cardiology*, *45*(8), 100618. https://doi.org/10.1016/j.cpcardiol.2020.100618

There have not been reports of candidates being listed for liver or intestine transplant as a result of COVID-19. The Lung Committee received feedback from Liver and Intestine Transplantation Committee leaders that COVID-19 infections were not likely to lead to a need for liver or intestine transplant. The Lung Committee is seeking additional feedback on whether COVID-19 patients could need a liver or intestine transplant as a result of damage from COVID-19.

Pancreas and Vascularized Composite Allograft (VCA)

It is currently unclear whether there is a connection between acute pancreatitis and COVID-19, and there is not currently evidence of any connection between COVID-19 and damage that would require a VCA transplant.[24] The Pancreas Transplantation Committee did not expect any pancreas candidates to be listed as a result of COVID-19. The Lung Committee is seeking feedback on whether COVID-19 diagnoses should be collected on pancreas or VCA candidates.

Diagnosis in Allocation

The Lung Committee proposes including both "COVID-19: acute respiratory distress syndrome" and "COVID-19: pulmonary fibrosis" in Diagnosis Group D (restrictive lung disease), outlined in *OPTN Policy 10.1.F.i Lung Disease Diagnosis Groups*. This is the Diagnosis Group in which ARDS and pulmonary fibrosis from non-COVID-19 causes are included.

The diagnosis group (A-D) that a candidate's diagnosis falls within directly impacts their LAS. These points are calculated based on the predicted likelihood of waiting list survival and post-transplant survival.[25] The diagnoses currently included in group D are restrictive lung disease diagnoses,[26] including "acute respiratory distress syndrome (ARDS)/pneumonia", which is consistent with the known progression of COVID-19,[27] and pulmonary fibrosis diagnoses which can develop from ARDS.[28]

Figure 1: Progression of COVID-19[29]

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[24] Thaweerat W. (2020). Current evidence on pancreatic involvement in SARS-CoV-2 infection. *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]*, *20*(5), 1013–1014. https://doi.org/10.1016/j.pan.2020.05.015

[25] The calculation of LAS is the subject of a related proposal currently published for public comment, the proposal for an *Updated Cohort for Calculation of the Lung Allocation Score (LAS)*, available at https://optn.transplant.hrsa.gov/governance/public-comment/updated-cohort-for-calculation-of-the-lung-allocation-score-las/. That proposal updates the patient population data used to determine the LAS to include candidates and recipients from March 1, 2015 to March 31, 2018 and removes factors that no longer help predict waitlist or post-transplant survival. That proposal will affect the specific coefficients used in the calculation for these candidates.

[26] When the LAS was developed, the OPTN looked at the expected one year waitlist and post-transplant survival of candidates with the four most common diagnoses, emphysema/COPD, idiopathic pulmonary fibrosis, Cystic Fibrosis and portopulmonary hypertension because it was anticipated that the survival rates would be different based on diagnosis. This proved to be true. Since the sample sizes for other diagnoses were not large enough to build reliable diagnosis-specific mortality models, the less common diagnoses were grouped together with the more predictive diagnoses. For those that had sufficient numbers to be somewhat predictive, the data was analyzed to determine which group was most appropriate, and for those that did not have enough statistical information upon which to base a grouping decision, the decision was made on clinical grounds.

[27] Zaim, S., Chong, J. H., Sankaranarayanan, V., & Harky, A. (2020). COVID-19 and Multiorgan Response. *Current problems in cardiology*, Table 2: Clinical syndromes associated with COVID-19 in adults.

[28] Paolo Spagnolo, Elisabetta Balestro, Stefano Aliberti, Elisabetta Cocconcelli, Davide Biondini, Giovanni Della Casa, Nicola Sverzellati, and Toby M Maher. "Pulmonary fibrosis secondary to COVID-19: a call to arms." *The Lancet, Respiratory Medicine,* May 15, 2020. DOI:https://doi.org/10.1016/S2213-2600(20)30222-8

[29] Ibid.

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The Lung Committee does not propose changing the categorization of these diagnoses as group D, which includes ARDS and pulmonary fibrosis, but proposes clearly identifying which of those patients' conditions have been brought on by COVID-19.

The Lung Committee discussed adding additional categories to further identify candidates with pre-existing conditions, such as chronic obstructive pulmonary disease (COPD), whose condition was significantly impacted by COVID-19. For these patients, a respiratory virus such as COVID-19 could exacerbate their COPD.[30] However, the Lung Committee preferred to continue to list these patients under their underlying, pre-existing disease, just as they would if another virus were the cause of the disease acceleration. In such cases, the impact of COVID-19 is not as clear as those where the lung disease was a direct result of COVID-19.

In current lung allocation policy, there is an option to request an exception if the transplant program does not believe the candidate's medical urgency is reflected in the LAS awarded based on their diagnosis. This will still be an option available in the instance that a specific patient's lungs are affected differently by COVID-19. Additionally, many differences in the health of such candidates would be accounted for in the LAS through the other measures of lung function that are used in the LAS equation.

Although the diagnosis is used in the calculation of LAS and allocation of lungs, other organ systems do not directly use the diagnosis in determining allocation order. Changes to add COVID-19 diagnosis options for any other organs would not require policy changes or affect the allocation order for those organs.

NOTA and Final Rule Analysis

The Lung Committee submits this proposal for community feedback under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[31] The OPTN shall "advise transplant hospitals of the information needed for … listing"[32] and "maintain records of all transplant candidates, all organ donors and all transplant recipients"[33] and shall "…receive…such records and information electronically…"[34] This proposal will allow the OPTN to collect more complete data on candidates who need a transplant as a result of COVID-19 and maintain such data in the OPTN dataset.

The Final Rule also requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall

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[30] Zheng, J., Shi, Y., Xiong, L., Zhang, W., Li, Y., Gibson, P. G., Simpson, J. L., Zhang, C., Lu, J., Sai, J., Wang, G., & Wang, F. (2017). The Expression of IL-6, TNF-α, and MCP-1 in Respiratory Viral Infection in Acute Exacerbations of Chronic Obstructive Pulmonary Disease. *Journal of immunology research*, *2017*, 8539294. https://doi.org/10.1155/2017/8539294.
[31] 42 CFR §121.11(b)(2).
[32] 42 CFR §121121.5(b).
[33] 42 CFR §121.11(a)(1)(ii).
[34] 42 CFR §121.11(a)(1)(iii).

be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment**[35] because it is an evidenced-based change relying on the following evidence:
  - Reports that patients with COVID-19 develop diagnoses that fall within diagnosis group D and are being listed and receiving lung transplants
  - Data showing the disease progression of patients who die from COVID-19
  - Data showing that COVID-19 causes organ damage
- **Seeks to achieve the best use of donated organs**[36] by ensuring organs are allocated and transplanted according to medical urgency. Adding the diagnosis to policy will provide the OPTN an opportunity to improve the mortality predictions in the future so that candidates with the same medical urgency are more likely to have similar LAS scores.
- **Is designed to avoid futile transplants**[37]**:** This proposal should not result in transplanting patients who are less likely to have favorable post-transplant outcomes. The LAS calculation balances waiting list mortality against post-transplant survival, and the diagnosis with which a candidate is listed factors into both parts of the equation. Adding the diagnoses to policy will also provide the opportunity for the OPTN to conduct post-implementation analysis to determine whether candidates transplanted after being diagnosed with COVID-19 have similar post-transplant outcomes to other lung transplant recipients.
- **Is not based on the candidate's place of residence or place of listing, except to the extent required to achieve** other regulatory requirements.[38] This proposal is not based on the candidate's place of residence or place of listing.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[39] and it is specific to an organ type, in this case lung.[40]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impact on the following aspects of the Final Rule:
- Is designed to avoid wasting organs[41]
- Is designed to…promote patient access to transplantation[42]
- Promotes the efficient management of organ placement[43]

The OPTN is providing the public with the opportunity to comment on these proposed policy changes in accordance with NOTA[44] and the OPTN Final Rule.[45]

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[35] 42 CFR §121.8(a)(1).
[36] 42 CFR §121.8(a)(2).
[37] Ibid.
[38] 42 CFR §121.8(a)(8).
[39] 42 CFR §121.8(a)(3).
[40] 42 CFR §121.8(a)(4).
[41] 42 CFR §121.8(a)(5).
[42] Ibid.
[43] Ibid.
[44] National Organ Transplant Act (NOTA), as amended, 42 USC §274(b)(2)(I).
[45] OPTN Final Rule 42 CFR § 121.4 (b)(1), and (e).

Implementation Considerations

Member and OPTN Operations

The Lung Committee proposes implementing these changes to add lung diagnoses in group D. No transition procedures are necessary for this proposal, since there is not any group that would be disadvantaged by the changes. There are not candidates on the waiting list and awaiting transplantation prior to the implementation date of this policy change that will be treated less favorably than they would have been treated under the current policy. The proposal does not modify where any candidates currently awaiting transplant will appear on a match run, it instead simply defines the diagnoses more specifically for these patients.

As soon as possible following Board approval, the OPTN will implement these changes using an expedited timeline to allow collection of these data as quickly as possible given the fact that COVID-19 is a public health emergency, and these data have the potential to help with understanding long term impacts.

Operations affecting Transplant Hospitals

Transplant hospitals will have additional options when reporting candidate diagnoses, and may need to educate staff or coordinate with electronic medical records vendors.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations (OPOs)

This proposal is not anticipated to affect the operations of OPOs.

Operations affecting the OPTN

The proposal will require programming of changes in UNet.

Projected Fiscal Impact

Minimal or no fiscal impact to members.

Projected Impact on the OPTN

It is estimated that it will take less than 150 hours to implement this proposal.

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."[46] The proposed language will not change the current routine monitoring of OPTN members. Any data entered into UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[47]

This data collection proposal will be formally evaluated at approximately 3 months, 6 months, and 1 year post- implementation. The following metrics, and any subsequently requested by the committee will be evaluated as data become available (appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet). For candidates and recipients with a COVID diagnosis the following metrics will be reported,

- The number of candidates by COVID diagnosis
- The demographics (age, gender, lung allocation score, and geographic area) of candidates by COVID diagnosis
- The number of recipients by COVID diagnosis
- The demographics (age, gender, lung allocation score, and geographic area) of recipients by COVID diagnosis
- The median time to transplant for candidates with a COVID diagnosis
- Comparison of the median time to transplant for candidates with a COVID diagnosis to those without a COVID diagnosis
- The waiting list mortality and post transplant patient survival rates for patients with a COVID diagnosis

Conclusion

Adding two COVID-19 diagnosis options for candidates listed for lung transplant will allow for faster identification of listing trends for these patients, and potential future refinements to the LAS calculation.

If appropriate and supported, similar diagnosis options could be added for other organ waitlists where it can be anticipated that there will be candidates listed for transplant as a result of damage from COVID-19. The Lung Committee would like feedback on:
- For lung, are there other diagnoses other than ARDS and pulmonary fibrosis that would be caused by COVID-19 and require lung transplantation?
- Are candidates for other organs being listed due to COVID-19 related organ failure?
- Should the OPTN establish COVID-19 related diagnosis codes for other organs?

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[46] 42 CFR §121.8(a)(7).
[47] 42 CFR §121.8(a)(6).

Policy Language

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2 **10.1.F.i Lung Disease Diagnosis Groups**

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

4
5 *Group A*
6 A candidate is in Group A if the candidate has *any* of the following diagnoses:

7
8 • Allergic bronchopulmonary aspergillosis
9 • Alpha-1 antitrypsin deficiency
10 • Bronchiectasis
11 • Bronchopulmonary dysplasia
12 • Chronic obstructive pulmonary disease/emphysema
13 • Ehlers-Danlos syndrome
14 • Granulomatous lung disease
15 • Inhalation burns/trauma
16 • Kartagener's syndrome
17 • Lymphangioleiomyomatosis
18 • Obstructive lung disease
19 • Primary ciliary dyskinesia;
20 • Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
21 • Tuberous sclerosis
22 • Wegener's granuloma – bronchiectasis
23
24 *Group B*
25 A candidate is in Group B if the candidate has any of the following diagnoses:
26
27 • Congenital malformation
28 • CREST – pulmonary hypertension
29 • Eisenmenger's syndrome: atrial septal defect (ASD)
30 • Eisenmenger's syndrome: multi-congenital anomalies
31 • Eisenmenger's syndrome: other specify
32 • Eisenmenger's syndrome: patent ductus arteriosus (PDA)
33 • Eisenmenger's syndrome: ventricular septal defect (VSD)
34 • Portopulmonary hypertension
35 • Primary pulmonary hypertension/pulmonary arterial hypertension
36 • Pulmonary capillary hemangiomatosis
37 • Pulmonary telangiectasia – pulmonary hypertension
38 • Pulmonary thromboembolic disease
39 • Pulmonary vascular disease
40 • Pulmonary veno-occlusive disease

41 • Pulmonic stenosis
42 • Right hypoplastic lung
43 • Scleroderma – pulmonary hypertension
44 • Secondary pulmonary hypertension
45 • Thromboembolic pulmonary hypertension
46
47 ***Group C***
48 A candidate is in Group C if the candidate has *any* of the following diagnoses:
49
50 • Common variable immune deficiency
51 • Cystic fibrosis
52 • Fibrocavitary lung disease
53 • Hypogammaglobulinemia
54 • Schwachman-Diamond syndrome
55
56 ***Group D***
57 A candidate is in Group D if the candidate has *any* of the following diagnoses:
58
59 • ABCA3 transporter mutation
60 • Alveolar proteinosis
61 • Amyloidosis
62 • Acute respiratory distress syndrome or pneumonia
63 • Bronchioloalveolar carcinoma (BAC)
64 • Carcinoid tumorlets
65 • Chronic pneumonitis of infancy
66 • Constrictive bronchiolitis
67 • COVID-19: acute respiratory distress syndrome
68 • COVID-19: pulmonary fibrosis:
69 • CREST – Restrictive
70 • Eosinophilic granuloma
71 • Fibrosing Mediastinitis
72 • Graft versus host disease (GVHD)
73 • Hermansky Pudlak syndrome
74 • Hypersensitivity pneumonitis
75 • Idiopathic interstitial pneumonia, with at least one or more of the following disease entities:
76   o Acute interstitial pneumonia
77   o Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
78   o Desquamative interstitial pneumonia
79   o Idiopathic pulmonary fibrosis (IPF)
80   o Nonspecific interstitial pneumonia
81   o Lymphocytic interstitial pneumonia (LIP)
82   o Respiratory bronchiolitis-associated interstitial lung disease
83 • Idiopathic pulmonary hemosiderosis
84 • Lung retransplant or graft failure: acute rejection
85 • Lung retransplant or graft failure: non-specific
86 • Lung retransplant or graft failure: obliterative bronchiolitis-obstructive

87   •   Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
88   •   Lung retransplant or graft failure: obstructive
89   •   Lung retransplant or graft failure: other specify
90   •   Lung retransplant or graft failure: primary graft failure
91   •   Lung retransplant or graft failure: restrictive
92   •   Lupus
93   •   Mixed connective tissue disease
94   •   Obliterative bronchiolitis: non-retransplant
95   •   Occupational lung disease: other specify
96   •   Paraneoplastic pemphigus associated Castleman's disease
97   •   Polymyositis
98   •   Pulmonary fibrosis: other specify cause
99   •   Pulmonary hyalinizing granuloma
100   •   Pulmonary lymphangiectasia (PL)
101   •   Pulmonary telangiectasia – restrictive
102   •   Rheumatoid disease
103   •   Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
104   •   Scleroderma – restrictive
105   •   Secondary pulmonary fibrosis: (specify cause)
106   •   Silicosis
107   •   Sjogren's syndrome
108   •   Surfactant protein B mutation
109   •   Surfactant protein C mutation
110   •   Teratoma
111   •   Wegener's granuloma – restrictive