

Notice of OPTN Policy, Guidelines, and Guidance Changes

Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution

Sponsoring Committee:	OPTN Lung Transplantation Committee
Policies Affected:	<i>10.2.C: Review of Exceptions</i> <i>10.2.D: Appeals to Lung Review Board</i> <i>10.2.E: Appeals to Lung Transplantation Committee</i>
Guidance Affected:	<i>Lung Review Board Guidance</i>
Guidelines Affected:	<i>Lung Review Board Operational Guidelines</i>
Public Comment:	August 3, 2022 – September 28, 2022
Board Approved:	December 5, 2022
Effective Date:	Upon implementation of the proposal <i>Establish Continuous Distribution of Lungs</i>¹

Purpose of Policy, Guidelines, and Guidance Changes

To promote a consistent review of exception requests for lung transplant candidates in the continuous distribution allocation system, the OPTN will implement:

- Operational guidelines that outline representation, responsibilities, and process for the Lung Review Board
- Clinical guidance regarding information that transplant programs should provide when submitting an exception request, and that review board members should consider when evaluating an exception request
- Policy changes to improve consistency across organs in terms of where members can find information on review boards between operational guidelines, guidance, and policy

Proposal History

The OPTN Board of Directors approved the proposal *Establish Continuous Distribution of Lungs*² in December 2021.³ This proposal established a new Lung Review Board (Review Board) in policy but did not provide operational guidelines for the review board or clinical guidance for submitting exception requests. The OPTN Lung Transplantation Committee (Committee) subsequently released a proposal for

¹ "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, accessed November 30, 2022, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

² Ibid.

³ December 6, 2021 Board of Directors Meeting, OPTN, Executive Summary, accessed November 30, 2022, <https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf>.

public comment from August 3, 2022, to September 28, 2022, with operational guidelines, clinical guidance, and updates to policy regarding the Review Board.

In response to public comment feedback, the proposal was updated to strengthen pediatric representation on the Review Board, provide guidance on pediatric exception requests, and ensure that the Committee responds expediently to appealed exception requests.

Summary of Changes

As part of the implementation of continuous distribution of lungs, Review Board operations will be implemented in the OPTN Computer System. The OPTN will implement several other changes to Review Board operations in an effort to move towards a more consistent cross-organ framework as each organ committee evaluates shifting the respective organ allocation systems to continuous distribution. These changes include:

Review Board Representation

- The Review Board will have representatives from thirteen lung transplant programs, with each of the thirteen transplant programs appointing a primary review board member and an alternate
- Transplant programs must ensure that the primary representative has at least five years of post-training transplant experience and the alternate representative has at least three years of post-training transplant experience
- At least four of the thirteen transplant programs represented on the Review Board must have performed at least one transplant for a candidate under the age of 12 within the last five years
- The immediate past chair of the Committee will be the Chair of the review board
- The Chair will fill an advisory role and serve as a liaison between the Review Board and the Committee; the Chair will not be a voting member of the Review Board

Appeals

- If the Review Board denies an exception request, then the candidate's transplant program may appeal to the Review Board within seven days of receiving the denial, and the Review Board must review the appeal within 5 days of the date the appeal is submitted to the Review Board
- If the Review Board denies an exception request on appeal, then the candidate's transplant program may appeal to the Committee within seven days of receiving the denial, and the Committee must review the appeal no later than fourteen days following the request to the Committee

Guidance

- Outlines the type of information to include in an exception request
- Updates guidance for exceptions for candidates with pulmonary hypertension

Implementation

Transplant hospitals with active lung transplant programs will be able to appoint review board representatives to the new Lung Review Board on a regular basis. All lung transplant programs will not have representatives on the review board at all times. Appointed representatives will be expected to actively participate in the review board by voting on assigned cases within three days of case assignment. The Chair may remove members of the Review Board who the Chair identifies as non-responsive to Review Board cases.

These changes would be used to implement the review board for requests for exceptions to the components of the lung composite allocation score (CAS). The Review Board will begin work about a month before the CAS allocation changes take effect, in order to ensure that any needed exceptions can be awarded before the new scores impact allocation of lungs. Educational resources on the Review Board, exceptions process, and CAS will be available in the OPTN learning management system, UNOS Connect.

This proposal is not anticipated to affect the operations of organ procurement organizations or histocompatibility laboratories.

Affected Policy, Guidance, and Guideline Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

10.2.C Review of Exceptions

The Lung Review Board must review exception requests within five days of the date the request is submitted to the Lung Review Board. ~~If the Lung Review Board fails to make a decision on the initial exception request by the end of the five-day review period, the candidate will be assigned the requested exception score.~~

10.2.D Appeals to Lung Review Board

If the Lung Review Board denies an exception request, the candidate's transplant program may appeal to the Lung Review Board within seven days of receiving the denial. The Lung Review Board must review appeals within five days of the date the appeal is submitted to the OPTN Lung Review Board. ~~If the Lung Review Board fails to make a decision on the appeal by the end of the five-day appeal period, the candidate will be assigned the requested exception score.~~

10.2.E Appeals to Lung Transplantation Committee

If the Lung Review Board denies an exception request on appeal, the candidate's transplant program may appeal to the Lung Transplantation Committee within ~~fourteen~~ seven days of receiving the denial. The Lung Transplantation Committee must review the appeals at its next scheduled meeting no later than fourteen days following the request to the Committee.

Lung Review Board Guidance

Summary and Goals

Policy 10.2 allows a transplant program to submit exception requests for Medical Urgency, Post-Transplant Outcomes, Biological Disadvantages, and/or Patient Access Scores. The Lung Review Board (Review Board) provides prompt peer review of candidate score exceptions on the lung transplant waiting list. These guidelines are intended to promote consistent review of these scores.

When submitting an exception request, transplant programs must provide a clinical justification for the exception. Please refer to *Policy 10.2 Lung Composite Score Exceptions* for additional information about the exception review process.

This resource is not OPTN Policy, so it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or to define a standard of care. This resource is intended to provide guidance to transplant programs and the Review Board.

Recommendations

Exception Requests

In addition to the requirements listed in *OPTN Policy 10.2.B Exception Requests*, requesting transplant programs are encouraged to include citations to supporting literature where available. Transplant programs are encouraged to consult the CAS calculator, and the national score distribution information when considering what score to request, and may wish to include information in the request about how these were used in the choice of a requested score.

Pulmonary Hypertension

Lung transplant candidates diagnosed with pulmonary hypertension (PH) and who meet the following criteria may qualify for an increase in their Waitlist Survival and/or Post-Transplant Outcomes Scores:

1. Patient is deteriorating on optimal therapy, and
2. Patient has a right atrial pressure greater than 15 mm Hg or a cardiac index less than 1.8 L/min/m².

To request an increase in a PH candidate's scores, transplant programs must submit an exception request to the Review Board; this request should include sufficient clinical detail to support that the patient meets the above criteria.

If the transplant program believes that its patient has similar waiting list mortality and potential transplant benefit as a PH patient meeting the criteria listed above, then it should provide a detailed narrative on that assertion, referencing literature supporting the request for a higher score.

Transplant programs may wish to submit to the Review Board exception requests for the candidate's Waitlist Survival Score and Post-Transplant Outcomes Score to be at the national 90th percentile for each goal. This information is provided by the OPTN on a rolling basis.

Pediatric Priority 1

To request a pediatric priority 1 exception for a candidate currently assigned to priority 2, transplant programs should request an exception for 7.6292% of the waitlist survival score to get the 1.9073 waitlist points assigned to pediatric priority 1 candidates. It is not necessary to request an exception for

post-transplant outcomes since pediatric priority 1 and 2 candidates are assigned the same number of post-transplant outcomes points.

Lung Review Board Operational Guidelines⁴

Repealed.

Lung Review Board Operational Guidelines

Overview

The purpose of the Lung Review Board (Review Board) is to provide fair, equitable, and prompt peer review of exception requests. The Review Board will review these exception requests and determine if the request is comparable to other candidates with the same score.

Representation

Policy 10.2 Lung Composite Score Exceptions sets the structure and composition of the Review Board.

The membership of the Review Board is comprised of representatives from active lung transplant programs. Review Board members serve a term of 2 years. Service terms will be staggered among the Review Board members with a portion of active lung transplant programs permitted to appoint representatives each term. The Review Board membership is rotated to ensure each transplant program has equal opportunity to participate. Each participating lung transplant program may appoint a primary and an alternate representative. At least 4 of the active lung transplant programs must have performed at least one transplant for a candidate under the age of 12 within the last five years. The Review Board members from lung transplant programs that have performed at least one transplant for a candidate under the age of 12 within the last five years will be given priority for assignment to pediatric cases if they are available.

The immediate past Chair of the Lung Transplantation Committee will serve as the Review Board Chair for a 2-year term. In the event of a Review Board Chair vacancy, the Lung Transplantation Committee Chair will appoint a Review Board Chair.

Qualifications to serve on the Review Board include:

- The Review Board representative must be employed at an active lung transplant program.
 - If a transplant hospital inactivates or withdraws its lung program, the Review Board representative from that hospital may not participate in the Review Board.
 - If a transplant hospital inactivates or withdraws its pediatric lung component, the Review Board representative from that hospital may not participate in the Review Board.
 - The term of the transplant program or component's representative on the Review Board ends upon program or component's inactivation or withdrawal from the OPTN. Should a transplant program reactivate, it may again have the opportunity to be represented on the Review Board during future rotations.
 - It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for the both the primary Review Board representative and the alternate from their program. Should a representative leave his transplant program, then the program's alternate representative will become the primary Review Board member. The departing member will be removed from the Review Board.

⁴ "Lung Review Board Information," OPTN, January 2015, accessed June 23, 2022, https://optn.transplant.hrsa.gov/media/2701/review_board_guidelines_lung.pdf.

- Complete a conflict of interest and confidentiality statement and orientation training prior to each term of service.
- The primary representative must have at least five years of post-training transplant experience.
- The alternate representative must have at least three years of post-training transplant experience.
- Transplant programs must ensure that Review Board volunteers from their programs meet these requirements.

Chair Responsibilities

The Review Board Chair:

- Serves as a liaison between the Review Board and the Lung Transplantation Committee.
- May remove members of the Review Board who the Chair identifies as non-responsive to Review Board cases.

Representatives Responsibilities

Review Board representatives must:

- Vote on all exception requests and appeals according to the timelines set by policy.
- When voting to deny an exception, provide constructive comments that are relevant to the candidate's clinical information and based on policy or guidance documents. These comments will be provided to the candidate's lung program.
- Notify the OPTN of any planned absences. Requests will not be assigned to representatives who indicate they are out of the office.

The alternate representative will only be assigned cases if the primary representative indicates they are out of the office.

Voting Procedure

The OPTN Contractor will send the exception request or appeal to nine of the Review Board members. If there are fewer than nine reviewers available, the OPTN Contractor will send the case to all available reviewers.

If the assigned Review Board member has not voted within three days of when the OPTN Contractor sends the application or appeal to the Review Board, then the request will be reassigned to another representative.

The Review Board will review all exception requests prospectively. The candidate will not receive the exception score unless or until it is approved.

Voting will close at the earliest of when:

- A majority of all assigned voters have voted to approve an exception request
- A majority of all assigned voters have voted to deny an exception request
- The timeline lapses for the Review Board members to vote on the exception request.
The Review Board will have five days to vote and exception requests will be decided as follows:

<u>Of the votes submitted, if...</u>	<u>The request is...</u>
<u>The majority vote to approve</u>	<u>Approved</u>
<u>The majority vote to deny</u>	<u>Denied</u>
<u>There is a tie</u>	<u>Approved</u>
<u>No votes are submitted</u>	<u>Approved</u>

A majority is more than half of the votes submitted.

Appeal Process

A candidate's lung program may appeal the Review Board's decision to deny an exception request within seven days of receiving the appeal denial notification. All representative comments of denied requests are provided to the lung program. The program must submit additional written information justifying or amending the requested exception and may include responses to the comments of dissenting Review Board representatives. This additional information will be provided to the Review Board representatives for further consideration. To the extent possible, the appeal will be considered by the same reviewers who considered the initial exception application. Exception requests appealed to the Review Board are adjudicated as described in Voting Procedure, above.

Following a denial on an appeal to the Review Board, the candidate's lung program can appeal to the Committee. The lung program must appeal within 7 days of notification. The program can provide additional written information justifying or amending the requested exception to be sent to the Committee. The Committee will approve or deny each appeal no later than fourteen days following the request to the Committee. Exception requests appealed to the Committee are adjudicated as follows:

<u>Of the votes submitted, if...</u>	<u>The request is...</u>
<u>The majority vote to approve</u>	<u>Approved</u>
<u>The majority vote to deny</u>	<u>Denied</u>
<u>There is a tie</u>	<u>Approved</u>

Any member of the Committee who reviewed the case as a Review Board representative must abstain from voting on the appeal to the Committee.