Notice of OPTN Policy, Bylaw, and Guidelines Changes

Creation of OPTN Heart and Lung Committees

Sponsoring Committee: Thoracic Organ Transplantation

Policies Affected: 3.7.A: Applications for Modifications of Waiting Time
6.4.A: RRB and Committee Review of Status Exceptions
6.4.A.ii: Committee Appeals
10.2.B: Lung Candidates with Exceptional Cases
10.2.B.i: LRB Review Process
10.2.B.ii: LRB Decision Overrides
10.2.B.iii: Estimated Values Approved by the LRB
10.2.B.iv: LAS Diagnoses Approved by the LRB
10.2.B.v: LAS Approved by the LRB

Bylaw Affected: Article VII: Permanent Standing Committees

Board Approved: March 10, 2020

Effective Date: July 1, 2020

Summary of Changes

This proposal dissolves the Thoracic Organ Transplantation Committee (Thoracic Committee) and creates two new OPTN committees in its place: the Lung Transplantation Committee (Lung Committee) and the Heart Transplantation Committee (Heart Committee). Policy, Bylaw, and Guideline changes clarify or assign responsibilities that are currently specified as “Thoracic Committee” to “Lung Committee” or “Heart Committee” as appropriate.

Purpose of Changes

This will allow for more complete and balanced representation of the thoracic community when developing changes to heart and lung transplant policies. This proposal will also authorize additional staffing and financial resources to support presumed increases in heart and lung policy-related work.

Implementation

The OPTN published a call for nominations for volunteers for the new committees through March 25, 2020. Members were invited to participate in the nomination process for regional and at large representatives for both the Heart and Lung Committees. New committee members and leadership positions will be approved by the current OPTN Vice President consistent with the standard committee appointment process.

The new committees will officially begin work on July 1, 2020.
3.7 Waiting Time Modifications

3.7.A Applications for Modifications of Waiting Time

To apply for a waiting time modification, the candidate’s transplant program must submit an application to the OPTN Contractor with all of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. Documentation or a statement showing that the candidate qualified for the waiting time according to the organ-specific OPTN Policies 6 through 12.
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate’s physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

Upon receipt of a complete application and required documentation, the OPTN Contractor will forward the application, without person-identified data, according to Table 3-4 that follows:

<table>
<thead>
<tr>
<th>If the candidate requests a waiting time modification for the following organ:</th>
<th>Then the application will be reviewed by the:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>Kidney Waiting Time Modifications Subcommittee</td>
</tr>
<tr>
<td>Liver</td>
<td>A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee</td>
</tr>
<tr>
<td>Thoracic</td>
<td>A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee</td>
</tr>
<tr>
<td>Heart</td>
<td>A subcommittee of the Heart Transplantation Committee, appointed by the Chair of the Heart Transplantation Committee</td>
</tr>
<tr>
<td>Lung</td>
<td>A subcommittee of the Lung Transplantation Committee, appointed by the Chair of the Lung Transplantation Committee</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Kidney or Pancreas Waiting Time Modifications Subcommittee</td>
</tr>
<tr>
<td>Intestine</td>
<td>A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee</td>
</tr>
</tbody>
</table>
Waiting list modification applications will be reviewed as follows:

1. The reviewer will determine if it is appropriate to modify the candidate’s waiting time as requested in the application and will notify the OPTN Contractor of the decision.
2. Upon notice, the OPTN Contractor will implement the waiting time modification.
3. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.
4. The Committee will report the modification, without person-identified data, to the Board of Directors.

**6.4.A RRB and Committee Review of Status Exceptions**

The heart RRB reviews applications for adult and pediatric status exceptions and extensions retrospectively.

If the candidate is transplanted and the RRB does not approve the initial exception or extension request or any appeal, then the case will be referred to the Thoracic Heart Transplantation Committee. If the Thoracic Heart Transplantation Committee agrees with the RRB’s decision, then the Thoracic Heart Transplantation Committee may refer the case to Membership & Professional Standards Committee (MPSC) for review according to Appendix L of the OPTN Bylaws.

**6.4.A.ii Committee Appeals**

If the RRB denies the appeal, the candidate’s transplant program must within 1 day of receiving notification of the denied appeal either appeal to the Thoracic Heart Transplantation Committee or assign the candidate to the status for which the candidate qualifies. If the Thoracic Heart Transplantation Committee agrees with the RRB’s decision, the candidate’s transplant program must assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If the transplant program does not assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal, then the Committee will refer the case to the MPSC.

**10.2.B Lung Candidates with Exceptional Cases**

The Thoracic Organ Lung Transplantation Committee establishes guidelines for special case review by the LRB.

If a candidate’s transplant program believes that a candidate’s current priority or LAS does not appropriately reflect the candidate’s medical urgency for transplant, the transplant program may request approval of a specific priority or LAS by the LRB. The transplant program can also ask the LRB to approve specific estimated values or diagnoses.

For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate for the purposes of Policy 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old and Policy 10.4.D: Allocation of Lungs from Deceased Donors Less than 18 Years Old. Candidates receiving this exception will also maintain their pediatric
classification for the purposes of Policy 10.4.D: Allocation of Lungs from Deceased Donors Less than 18 Years Old.

10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, specific LAS, or adolescent classification exceptions require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN Contractor, and accompany each request for special review with a supporting narrative. The LRB will have seven days to reach a decision regarding the request, starting from the date that the OPTN Contractor sends the request to the LRB.

If the LRB denies a request upon initial review, then the transplant program may choose to appeal the decision and request reconsideration by the LRB. The transplant program has seven days from the date of the initial denial of the initial request to appeal. The LRB has seven days to reach a decision on the appeal, starting from the date that the OPTN Contractor sends the appealed request to the LRB. If the LRB does not complete its review of an initial request or appeal within seven days of receiving it, then the candidate will not receive the requested LAS, diagnosis, estimated value, or adolescent classification, and the OPTN Contractor will send the request or appeal to the Thoracic Organ Lung Transplantation Committee for further review.

Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB review by the LRB.

10.2.B.ii LRB Decision Overrides

If the LRB denies a transplant hospital’s initial request or appeal for an estimated value, adolescent classification, or specific LAS on appeal, the transplant hospital has the option to override the decision of the LRB. If the transplant hospital elects to override the decision of the LRB, then the OPTN Contractor will send the request or appeal to the Thoracic Organ Lung Transplantation Committee for review. This review by the Thoracic Organ Lung Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee (MPSC). If the MPSC agrees with the Thoracic Organ Lung Transplantation Committee’s decision, a member who has registered a candidate with an unapproved estimated value, adolescent classification, or LAS will be subject to action according to Appendix L: Reviews, Actions, and Due Process of the OPTN Bylaws.

10.2.B.iii Estimated Values Approved by the LRB

Approved estimated values approved by the LRB or Thoracic Organ Lung Transplantation Committee are valid until an actual value is reported to the OPTN Contractor or a new estimated value is reported to the OPTN Contractor.

10.2.B.iv LAS Diagnoses Approved by the LRB

A diagnosis that has been approved by the LRB or the Thoracic Organ Lung Transplantation Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved by the LRB.
10.2.B.v  LAS Approved by the LRB

An LAS approved by the LRB or the Thoracic Lung Transplantation Committee will remain valid for six months from the date the candidate’s LAS is updated, (or from the candidate’s twelfth birthday, whichever occurs later). If the candidate is still on the waiting list six months after the date the LAS is updated, then the candidate’s LAS will be computed as described in Policy 10.1: Priorities and Score Assignments for Lung Candidates unless a new LAS or priority request is submitted to the OPTN Contractor.
Article VII: Permanent Standing Committees

The OPTN will have the following permanent standing Committees:

- Ethics
- Heart Transplantation
- Histocompatibility
- Kidney Transplantation
- Liver and Intestinal Organ Transplantation
- Living Donor
- Lung Transplantation
- Membership and Professional Standards
- Minority Affairs
- Operations and Safety
- Organ Procurement Organization
- Pancreas Transplantation
- Patient Affairs
- Pediatric Transplantation
- Policy Oversight Committee
- Thoracic Organ Transplantation
- Transplant Administrators
- Transplant Coordinators

The Committees are advisory to the Board of Directors, which makes the final decisions of the OPTN. The standing Committees will provide initial review and analysis of proposed policies and initiatives based on their collective expertise and unique perspectives, and present their recommendations to the Board of Directors.

Committees may also be advisory to each other when Committee interest and expertise overlap. When Committees evaluate proposals jointly, they should present to the Board of Directors either a common recommendation or a report that summarizes the continued disagreement.

Committees may have additional responsibilities as defined by the OPTN Bylaws and Policies. Committees’ role in developing policies and standards is further defined in Article XI: Adoption of Policies of these Bylaws.
Affected Guidelines

New language is underlined (example) and language that is deleted is struck through (example). Only sections of Guidelines with approved changes are included here; sections of Guidelines not represented here are not affected.

OPTN Heart Review Board (HRB) Guidelines

5. Appeal Process

B. Appeals of HRB Denials to the Thoracic Heart Transplantation Committee and MPSC Review

If the HRB denies the appeal of an initial application or extension request application, the candidate’s transplant program must either appeal to the Thoracic Organ Heart Transplantation Committee (Committee) within 1 day of receiving notification of the denied appeal or assign the candidate to the status for which the candidate qualifies within 1 day of notification of the denied appeal.

The transplant program may provide the OPTN Contractor with additional information about the case, which the OPTN Contractor will send to the Committee. The Committee will approve or not approve each appeal within 7 days of submission of the case to the Committee.

Referral of cases to the Committee will include information about the number of previous case referrals from that transplant program and the outcome of those referrals.

If the application is not appealed to the Thoracic Heart Transplantation Committee within one day of receiving the notification of the HRB decision, the appeal process is not available.

OPTN Lung Review Board (LRB) Guidelines

2. Representation on the LRB

A. The LRB is composed of 9 individual lung transplant surgeons or lung transplant physicians, including 3 pediatric members selected in rotation from a national pool of active lung transplant programs that have agreed to participate on the LRB. Six LRB members represent active adult lung transplant programs and 3 members represent active pediatric lung transplant programs. The Chair of the OPTN/UNOS Thoracic Organ Lung Transplantation Committee (the Committee) shall appoint a primary LRB member from among those selected to serve as the LRB Chair for a 2-year term. Each active lung transplant program shall have the opportunity to rotate onto the LRB.

B. LRB members serve a term of 2 years. Service terms will be staggered among the LRB members to ensure that at no time more than 5 terms will end. This requirement is to preserve the continuity of the LRB and the efficiency of its operation. If additional LRB representatives are to be appointed to the LRB due to a change in the operational guidelines, the Chair of the Thoracic Lung Transplantation Committee will select the additional members and establish the terms of their initial appointment.

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