
Lung Review Board Information

Contents

Relevant Policy:.....	2
LRB Guidelines.....	4
Types of LRB Exceptions	11
Overview Data.....	14

Relevant Policy:

10.2.B Lung Candidates with Exceptional Cases

The Thoracic Organ 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 12 to Less Than 18 Years Old*. Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 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 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 Transplantation Committee for review. This review by the Thoracic Organ 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 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 Committee will be 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 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 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.

LRB Guidelines

1. Purpose of the LRB

The LRB provides prompt peer review of candidate priority and score exceptions on the lung transplant waiting list.

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 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 Committee will select the additional members and establish the terms of their initial appointment.
- C. Each LRB member is required to appoint an alternate representative from his transplant program.

It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for the both the primary LRB representative and the alternate from their program. Should a representative leave his transplant program, then the program's alternate representative will become the LRB member and another alternate will be appointed. The departing member is no longer a member of the LRB.

- D. If a lung program is inactivated, it is no longer entitled to representation on the LRB. The term of the transplant program's representative on the LRB ends upon withdrawal or inactivation. Another eligible transplant program will be contacted at random and requested to put forth a representative and an alternate to replace the departed member. Should a transplant program reactivate, it may again have the opportunity to be represented on the LRB during future rotations.

3. Responsibilities of the LRB Members

LRB members and alternates must:

- A. Evaluate the appropriateness of applying the requested priority, estimated clinical values, diagnosis, requested LAS or adolescent candidacy to the specified applicant.
- B. Vote on cases according to the timelines specified in the OPTN/UNOS policies and guidelines.
- C. Participate on conference calls as they are scheduled.
- D. Sign an OPTN/UNOS Confidentiality/Conflict of Interest Statement prior to serving on the LRB.

4. Voting Procedures

A. Eligibility to Vote

An LRB member or alternate's vote will not be valid and will not count towards quorum in any case in which he has a conflict of interest. The vote of an LRB member on cases originating from his transplant program or hospitals where he has an affiliation will be excluded from the final vote count.

B. Retrospective Review of Status Exceptions

The LRB will retrospectively review each Priority exception application. The review will address the appropriateness of the Priority assignment.

During the entirety of the retrospective review and appeal process, the candidate's priority will be equal to the requested priority, and the requesting program must follow all OPTN policies that apply to the requested priority.

At the termination of the application and appeal process, if the requested priority is not approved, then the requesting program must either change the candidate's priority to the priority for which the candidate qualifies under policy or follow the requirements for an override, as described below.

C. Prospective Review of Score Exceptions

The LRB will prospectively review requests for LAS scores; estimated clinical values; diagnoses; cases where the LAS is in dispute; and cases in which a candidate less than 12 years old requests to be registered as an adolescent candidate based on his or her LAS. The review will address the appropriateness of the existing LAS or priority, the appropriateness of the

requested value or LAS, and, where necessary, the appropriateness of registering a candidate under 12 years old as an adolescent.

During the prospective review and appeal process, the candidate will be registered according to the score or priority for which he qualifies under policy, until the OPTN Contractor notifies the requesting program that the request is approved by the LRB. Alternatively, the requesting program may follow the requirements for an override, as described below.

D. Initial LRB Case Review and Vote

The OPTN Contractor will send the application or appeal to LRB members. If the LRB member has not voted within 3 days of when the OPTN Contractor sends the application or appeal to the LRB, then the OPTN Contractor will send the case to the alternate. Thereafter, both the LRB member and alternate may vote on the application within 7 days of when the OPTN Contractor originally sent the application to the LRB. If the LRB member and the alternate both submit votes for the same application, then the OPTN Contractor will count the vote from whomever voted first.

Initial applications are decided as follows:

If the vote is...	And the case is prospectively reviewed, then the...	Or the case is retrospectively reviewed, then the...
Majority vote to approve the request	Application is granted	Application is granted
Majority vote to deny the request	Application is not granted	Application is not granted
Tie Vote	Application is not granted	Application is granted
No Quorum	Application is not granted	Application is granted

In order for a vote to be valid, quorum must be reached. To reach quorum, a majority of all LRB members, or their alternates in cases where the LRB member cannot or does not vote, eligible to vote must vote within the allotted timeframe.

A majority vote is calculated by dividing the total number of eligible LRB members that vote on each case by half and then adding one.

Voting will close at the earliest of when:

- all eligible voters have voted;
- a majority of all eligible voters have voted to approve or deny a request; or
- 7 days after the OPTN Contractor sends the request to the LRB.

Once voting has closed on a case, an LRB member or alternate can no longer vote on that case.

The OPTN Contractor will send the results of the LRB's vote to the requesting program. The OPTN Contractor must not reveal the vote of any specific LRB member, but may provide the requesting program with comments or questions made by the LRB members.

5. Appeals

A. Appeal to the Review Board

If the LRB does not grant the exception, then the requesting program may appeal the decision of the LRB. Individual candidates are not eligible to submit exception applications or appeal LRB rulings. Only transplant programs may submit applications and appeals.

The requesting program must notify the OPTN Contractor of its intent to appeal within 7 days of when the OPTN Contractor sent the requesting program notice of the initial RRB decision, and submit additional information justifying the requested exception, as well as responses to written comments of dissenting LRB members. This additional information will be submitted to LRB members for further consideration.

If the appeal is not approved, the requesting program may request a conference call with the LRB. A teleconference is considered an additional appeal.

If the LRB fails to reach quorum, or the vote results in a tie, within 7 days of the date the requesting program initially sent the appeal request to the OPTN Contractor, the OPTN Contractor will notify the requesting program of the result, and the requesting program may list the candidate at the requested priority or score.

Appealed applications are decided as follows:

If the vote is...	And the case is prospectively reviewed, then the...	Or the case is retrospectively reviewed, then the...
Majority vote to approve the request	Appeal is granted	Appeal is granted
Majority vote to deny the request	Appeal is not granted	Appeal is not granted
Tie Vote	Appeal is granted	Appeal is granted
No Quorum	Appeal is granted	Appeal is granted

B. Appeals of Denials to the Committee

If the LRB votes to deny the request for the entirety of 7 days from the date the OPTN Contractor sends the transplant program’s request for appeal to the LRB, then the requesting program may request a final appeal to the Committee. The requesting program must request the Committee appeal within 14 days of when the OPTN Contractor sent the requesting program notice of the LRB appeal decision.

The requesting program may provide the OPTN Contractor with additional information about the case, which the OPTN Contractor will send to the Committee or Lung Subcommittee. At its next scheduled meeting, the Committee or Lung Subcommittee will compare the eligibility criterion of other approved exceptional cases to achieve consistency in approved exception requests and to determine whether this candidate meets similar levels of medical urgency. The Committee will approve or deny each appeal according to its own procedures.

C. Overrides

If the LRB or Committee does not grant a request or appeal, then the requesting program may nonetheless implement the requested exception. The transplant program must notify the OPTN Contractor of its intent to do so. The OPTN Contractor will notify the Committee of the requesting program’s decision to override and provide any available details about the case.

The Committee will retrospectively discuss any overrides at its next scheduled full committee meeting or lung subcommittee meeting. The Committee or subcommittee will determine whether candidates the transplant program registered using the override process exhibited similar medical urgencies as other candidates registered at the requested score or priority. If the Committee or subcommittee determines any of these cases were not comparable to the other candidates registered at the same score or priority, then the Committee may refer the transplant program to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

D. Referrals for Committee Discussion and MPSC Review

The LRB may refer a case to the Committee if the final outcome of the LRB appeal is a denial of the request, a lack of quorum, or a tie vote. The Committee will discuss LRB cases that end in ties or quorum with the purpose of looking at LRB policies, guidelines and procedures. The LRB may refer a case to the Committee if the transplant program does not respond to requests for a statement of intent to appeal, or to subsequent requests to submit additional information in support of the appeal.

Referral of cases to the Committee will include information about the number of previous case referrals from that program and the outcome of those referrals. If the Committee or subcommittee determines any of these cases were not comparable to the other candidates registered at the same status, then the Committee may refer the registering hospital to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Additionally, the OPTN Contractor will refer the cases that result in a lack of quorum to the Committee or Lung Subcommittee. The Committee or Lung Subcommittee will review these cases to ensure that RRB members are properly executing their responsibilities outlined in Section 3.

6. Extensions

If an unapproved exception will expire before the deadline for an LRB or Committee to decide an appeal for that exception, and the program submits a request for an extension of that exception, then the LRB or Committee will vote on the exception extension request, and the appeal for the unapproved exception will automatically close out.

7. **Administration**

The central office for the LRB is maintained by the OPTN Contractor. The LRB efforts are coordinated by the OPTN Contractor with the help of the Chair of the LRB.

Data sent to the LRB for action or review will not contain transplant program, hospital or candidate identifying information.

Responses may be shared with the requesting program if an LRB member specifically asks that comments be shared with the program, regardless of the voting outcome.

When a new group of LRB members are identified, all lung transplant programs are notified of the roster. However, the only time an LRB member's identity as a reviewer is disclosed is during conference calls.

Types of LRB Exceptions

- Score Exceptions
 - If a program does not think that the candidate's calculated LAS is reflective of the candidate's actual medical urgency, it can submit a request for a specific score to the LRB for approval.
 - Approved exception scores are valid for 6 months.
 - Prospective approval required.
- Values Exceptions
 - If a program cannot obtain the value of a required LAS variable, it can submit an exception request to the LRB for approval of an estimated value. For example, if a program cannot perform a right heart catheterization, it may submit an estimated CVP or cardiac index value to the LRB for approval.
 - Values exceptions are valid until the program enters an updated value or requests an updated exception value.
 - Prospective approval required.
- Diagnosis Exceptions
 - If a candidate's primary diagnosis is not included on the list of diagnoses in Waitlist, then the program may submit an exception request to list the candidate with an "other" diagnosis. The request must specify which diagnosis group the "other" diagnosis belongs in.
 - On February 19, the following diagnoses were added to Waitlist:
 - Added to Group B
 - Pulmonary capillary hemangiomatosis
 - Added to Group D
 - ABCA3 transporter mutation
 - Idiopathic interstitial pneumonia (IIP), with at least one or more of the following disease entities:
 - Acute interstitial pneumonia
 - Desquamative interstitial pneumonia
 - Nonspecific interstitial pneumonia
 - Respiratory bronchiolitis-associated interstitial lung disease
 - Pulmonary lymphangiectasia (PL)
 - Secondary pulmonary fibrosis (specify cause)
 - Surfactant protein C mutation
 - Diagnosis exceptions are valid indefinitely unless the program seeks a change from the LRB.
 - Prospective approval required.
- Priority 1 Exception (pediatric candidates)
 - Programs may request to register a candidate that qualifies under policy for Priority 2 as Priority 1 if the program does not think that Priority 2 is reflective of the candidate's actual medical urgency.
 - Retrospective approval.

- Pulmonary Hypertension

- [Guideline:](#)

Guideline

Lung transplant candidates diagnosed with pulmonary hypertension (PH) and who meet the following criteria may qualify for an increase in their Lung Allocation Score (LAS):

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 LAS, transplant programs must submit an exception request to the Lung Review Board (LRB); 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 LAS. When submitting an exception request, transplant programs must provide a clinical justification for the exception. Please refer to [Policy 10.2.B \(Lung Candidates with Exceptional Cases\)](#) for additional information about the exception review process.

Policy 10.2.B allows a transplant program to submit an exception request for an LAS, an estimated value for one of the tests that is used to calculate the LAS, or assignment to a diagnosis group for a disease that is not listed in [WaitlistSM](#).

Note: The LRB will render clinical judgment on exception requests for higher LAS, diagnosis, or estimated value.

Transplant programs may wish to submit to the LRB an exception request for the candidate's LAS to be at the national 90th percentile (see table below).

The LAS for all active candidates greater than or equal to 12 years of age waiting for lung transplants as of May 22, 2015 are as follows:

Number waiting	25 th percentile	Median	75 th percentile	90 th percentile	95 th percentile	99 th percentile
1,323	33.3	35.7	41.1	50.3	58.8	86.9

If you have questions, please contact the [UNetSM](#) Help Desk at 1-800-978-4334 or unethelpdesk@unos.org. You may also contact your review board staff member:

Regions 1 to 11 – Aaron McKoy (804) 782-6575

- Adolescent Classification Exception

- [Guideline:](#)

Memo To: Thoracic Transplant Clinicians

From: Steven A. Webber, MD, MBChB, MRCP

Chair, Thoracic Organ Transplantation Committee

Recommendation for Submitting Information and Evidence in Support of Lung Review Board (LRB) Exception Requests

Under Policy 3.7.6.4, transplant programs may submit requests to the LRB for “approval of estimated values, diagnosis, or a specific Lung Allocation Score, and in the case of candidates aged 0-11 years old, transplant programs may request classification as an adolescent candidate.” The Thoracic Organ Transplantation Committee offers the following guidance to transplant programs for submitting to the LRB information and evidence in support of exception requests:

- Primary reason for LRB exception request
- Candidate’s diagnosis and demographics, including age, gender, and size
- Candidate’s recent clinical history including hospital admissions, comorbidities, and the clinical course of disease
- Current support, i.e. oxygen supplementation, type and level of ventilatory support, use of ECMO or artificial lung
- Most recent objective evidence of patient deterioration if applicable (e.g. elevation in PaCO₂ and/or right atrial pressure, FiO₂ requirements, decrease in cardiac index, etc.)
- If candidate has PAH, provide evidence the candidate meets eligibility for LAS exception at the 90th percentile and a description of candidate’s treatment regimen, if applicable
- Explanation of why the candidate should be registered as an adolescent in addition to maintaining pediatric registration, if applicable

The list provided is not exhaustive, but is an example of the important detailed information the LRB will consider before making an informed determination in any LRB case. Applications that are considered inadequate for decision-making will be denied with explanation. Reapplication for LRB exceptions is accepted.

For all requests, OPTN/UNOS Staff will provide the LRB members with a copy of the candidate’s current WaitlistSM record. Transplant programs should ensure that the candidate’s clinical data is up to date in UNetSM.

- If you have questions, please contact Aaron McKoy (804) 782-6575.

Overview Data

Figure 1. LRB requests submitted 2006-2014, based on full cohort

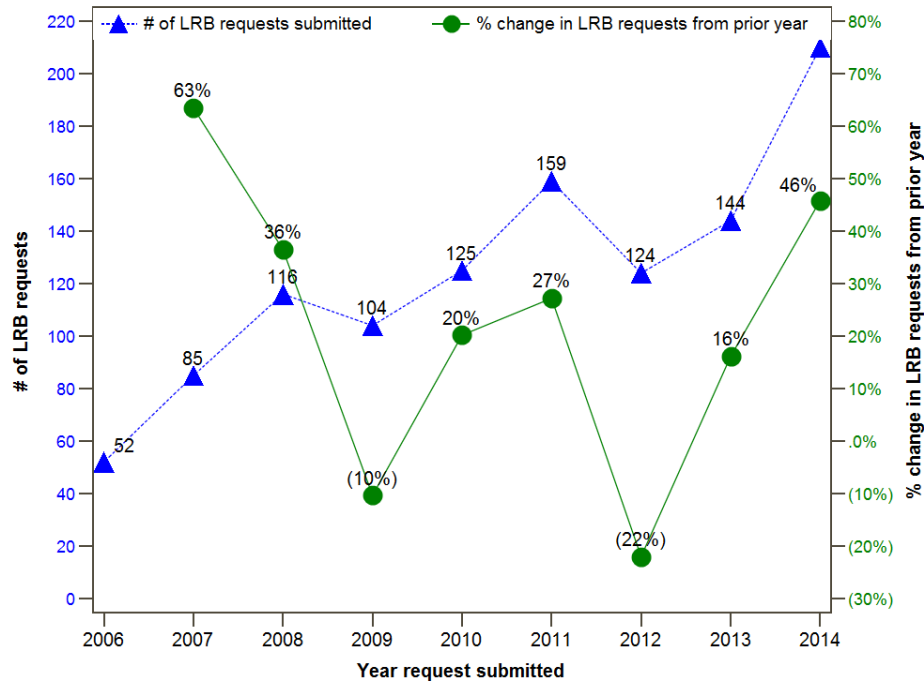


Figure 2. LRB requests submitted per year by request type, based on full cohort

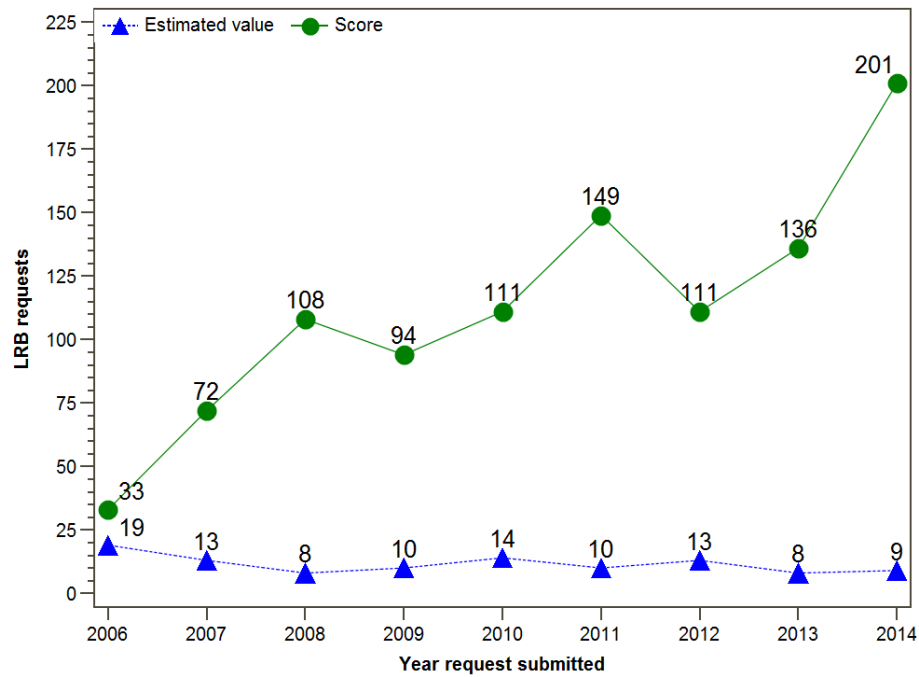


Figure 3. LRB requests submitted per year by diagnosis grouping, based on full cohort

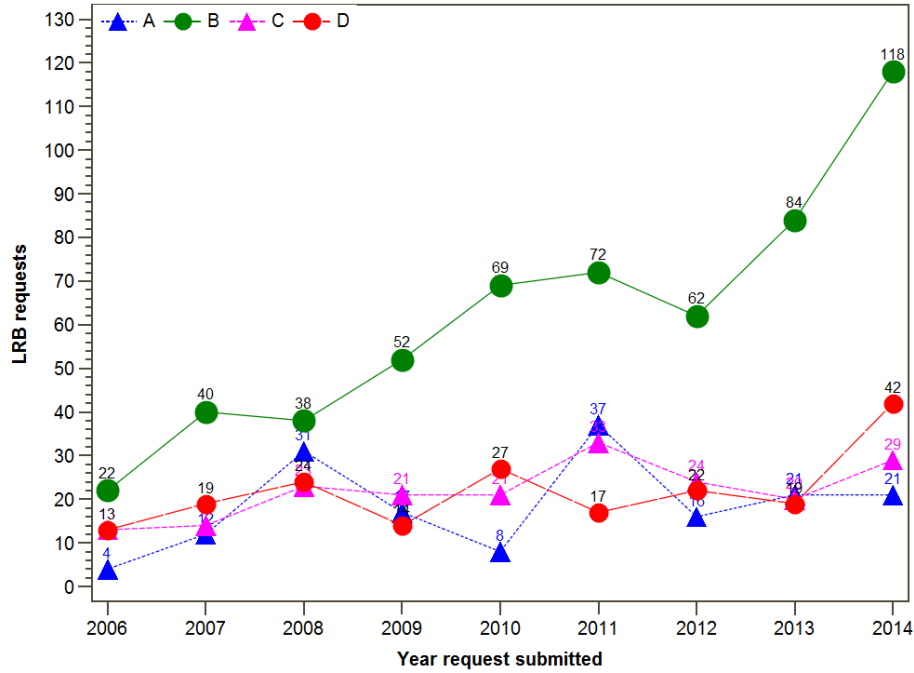


Figure 4. Average LRB requests per 100 candidate actively waiting, based on full cohort

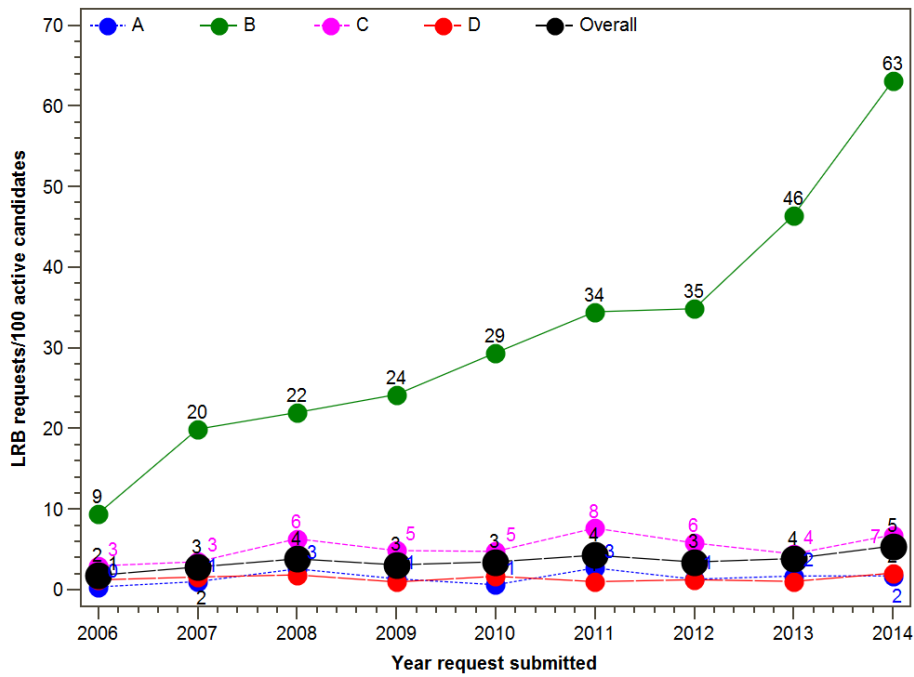


Figure 5. Percentage of requests that were approved, based on decision cohort

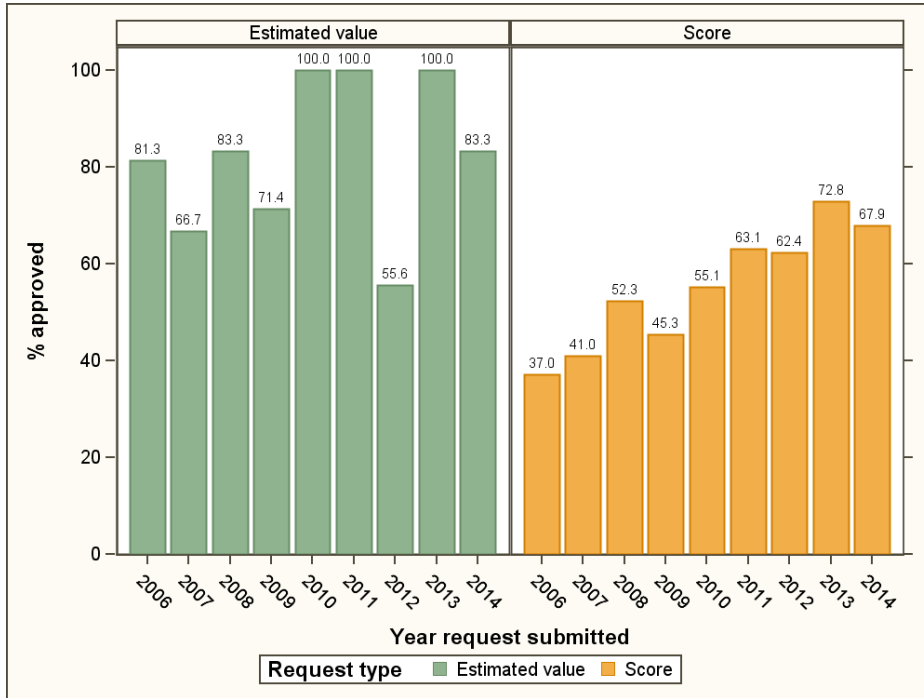
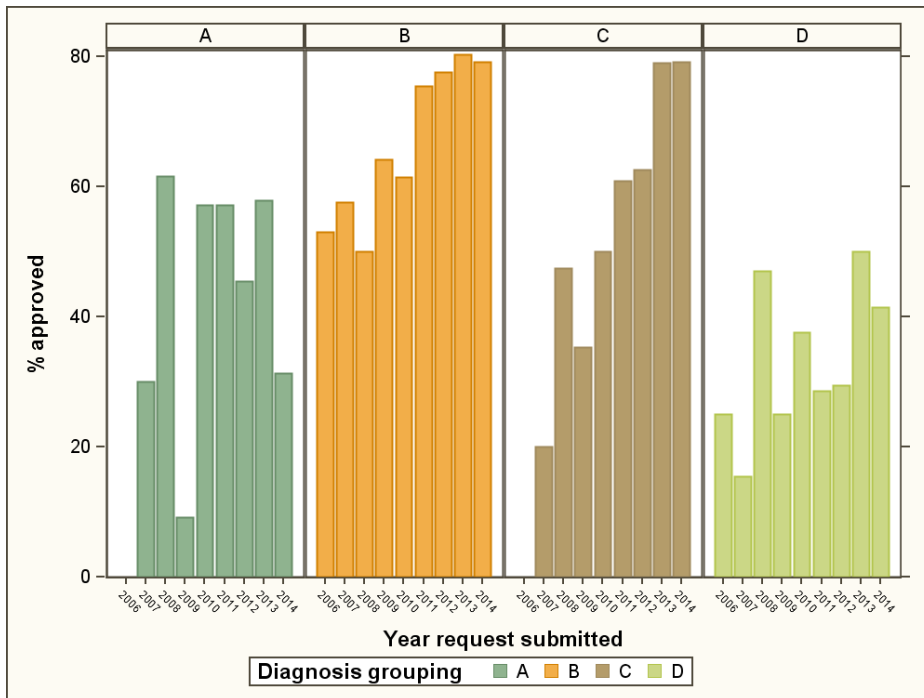


Figure 6. Percentage of score requests approved by diagnosis grouping, based on decision cohort



Adolescent Classification Exception Requests as of June 19, 2015

- 15 patients have ever had an adolescent exception.
 - 2 patients turned 12 years old prior to removal from the waiting list, leading to the removal of their adolescent exception registrations. Both were transplanted.
- These 15 patients have been listed at 7 different programs
- Removals/current status:
 - 2* patients still waiting with an adolescent exception registration
 - 8* patients have been transplanted (including the 2 who turned 12 years old while waiting):
 - 1 patient received adult (18+ years) donor lungs
 - 1 patient received adolescent (12-17 years) donor lungs
 - 6 patients received young pediatric (0-11 years) donor lungs
 - 3 patients died
 - 2 patients were removed as too ill to transplant
 - 1 patient was removed for other reasons

* There are 2 patients with 2 adolescent exceptions. One had the same outcome for both, so appears only once in the waiting list status counts above. The other was removed for transplant, and then relisted and is still waiting. This patient appears twice in the counts above, as still waiting and as transplanted.