

Rescind Approved Changes to the Pediatric Heart Status 1A Justification Form

Thoracic Organ Transplantation Committee

*Steve Webber, M.B.Ch.B., MRCP, Chair
June 24-25, 2013*

Background

- June 2010, Board approved modifications to Pediatric Heart Status 1A Justification Form
 - Collect granular data on mechanical circulatory support devices (MCSD)
 - These changes are not programmed yet
- Status justification forms submitted upon registration, or if candidate's condition changes
- MCSD data not required unless it is used to justify a candidate's status

The Problem

- Modifications to waiting list removal page are already programmed
- MCSD data collected on waiting list removal page
- Data collected is more comprehensive
 - Every MSCD ever implanted, even if not used to justify a candidate's status
 - Reporting occurs retrospectively

Impact of Approval

- No additional programming required
- Redundant information will not be collected
- Programming request will be removed from the queue

Cost Savings

UNOS Staff Resources: June 2010 Implementation Effort Estimate

Department	Implementation Staff Hours Estimate*
Communications	10
Corporate Counsel	0
Evaluation and Quality (DEQ)	50
Information Technology (IT)	930
Policy/Membership/Regional Administration (PMR)	30
Professional Services	0
Research	20
Implementation Estimate (hours and cost)**	1040 hours \$59,008

Resolution 7

RESOLVED, that approval for programming in the Pediatric Heart Status 1A Justification Form to separate the existing ventricular assist device (VAD) and extracorporeal membrane oxygenation (ECMO) data element into different fields, collect VAD device brand and type, collect VAD implant date, collect ECMO cannulation date, collect total artificial heart (TAH) device brand and implant date, and enable a center to enter data for all mechanical circulatory support devices that were in use, previously granted by the Board of Directors in June 2010 is hereby rescinded, effective June 25, 2013.

**Page 16 of Board book*

Guidance Regarding Policy 3.7.3: Adult Heart Status 1A(b) Device- Related Complications

Thoracic Organ Transplantation Committee

*Steve Webber, M.B.Ch.B., MRCP, Chair
June 24-25, 2013*

Background

- Policy 3.7.3 Status 1A(b) applies to adult heart candidates with “mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. “
- Transplant programs can report an “other” complication, subject to Regional Review Board (RRB) approval

The Problem

- Variability in exception applications regarding “other” complications
- Lack of uniform definitions
- RRBs do not have any guidance

Collaboration

- Heart Subcommittee worked with INTERMACS to align MCSD “device infection” and “device complication” definitions where appropriate

Audience

- RRB members can use the guidance document to help determine whether to approve an “other” application under 3.7.3 Status 1A(b)
 - RRB member discretion still permitted
- Transplant programs can use the guidance document to help determine whether the Status 1A(b) application is sufficient

Resolution 8

RESOLVED, that the guidance document “Guidance Regarding Policy 3.7.3: Adult Heart Status 1A(b),” as set forth in Exhibit C to the Thoracic Committee’s report to the Board, is hereby approved, effective June 25, 2013.

**Page 17 of Board book*

Approve Changes to the OPTN/UNOS Lung Review Board (LRB) Guidelines for Reviewing LAS and Priority Exceptions

Thoracic Organ Transplantation Committee

*Steve Webber, M.B.Ch.B., MRCP, Chair
June 24-25, 2013*

Background

- June 2013 Executive Committee approves policy to permit lung candidates less than 12 years old to submit exception requests to the Lung Review Board (LRB) to be registered as an adolescent candidate (12- less than 18 years old)
- If LRB approves exception request, candidate will have 2 waiting list registrations
 - Candidate retains current priority registration
 - Allocation for this registration according to priority and waiting time
 - New wait list registration created for candidate with 12 year-old birthday
 - Allocation for this registration according to LAS

The Problem

- Current LRB Guidelines silent on this type of request
- Current LRB membership does not have enough pediatric expertise

Changes to Guidelines

- **Change the composition of the LRB**
 - From 7 total members to 9 total members
 - From 1 pediatric representative to 3 pediatric representatives
 - First additional pediatric reps will be chosen by Thoracic Committee Chair
- **Pediatric reps will review all pediatric and adult cases**
- **Add adolescent request cases to Prospective Review section**

Resolution 18

RESOLVED, that the modifications to the Lung Review Board guidelines, as set forth in Exhibit S to the Thoracic Committee's report to the Board, are hereby approved, effective June 25, 2013.

Questions?