Anticipated Impact of the Revised UNOS Adult Heart Allocation System, Effective September 2018, on MCS Device Recipients
Introduction

Starting in September 2018, the revised UNOS adult heart allocation system goes into effect. This guide provides an overview of the changes to the medical urgency statuses of mechanical circulatory support (MCS) device recipients and commentary on how these changes may impact MCS device use.

Today, heart transplantation is the gold standard for patients suffering from advanced and end-stage heart failure. However, the existing United States adult heart allocation system, which is based on medical urgency (those with the highest pre-transplant mortality) and benefit gained from transplantation (those with the highest post-transplant survival potential), faces two major challenges:

- A rapidly growing transplant waiting list with limited donor heart availability
- Evolving and expanding use of temporary and durable MCS devices to treat advanced and end-stage heart failure

Since the last revision of the heart allocation system in 2005, technological advances in device therapy, improved patient selection criteria and increased clinician experience with device management have resulted in improvements in outcomes for advanced heart failure patients. In response to these advances and challenges, the United Network for Organ Sharing (UNOS) created a revised adult heart allocation system that will go into effect starting in September 2018.

The revised system is intended to create a fairer and more equitable allocation of donor hearts in the United States in order to reduce waiting list mortality among the most urgent heart transplant candidates.

The revised system will be implemented in two phases. During Phase I, which begins September 18, 2018, new forms for justifying patient medical urgency status will be implemented. During Phase II, which begins October 18, 2018, full implementation of the adult heart allocation policy will go into effect.

The most significant revision to the allocation system is the expansion of the three existing medical urgency statuses (Status 1A, 1B and 2) to six (Status 1 – 6). Under the revised system, patients in the current 1A status have been stratified into three groups of decreasing severity.

In addition, the revised medical urgency statuses allow for greater distinctions between the different types of MCS devices currently available, including whether a patient is on a temporary or durable MCS device, and whether the patient requires biventricular support or replacement or single ventricular support.

The tables on the following pages outline the stratification of Status 1A (page 3) and the criteria for determining a patient’s medical urgency under both the current system (page 4) and the revised system (page 5).

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Stratification of Adult Heart Allocation Medical Urgency Statuses

<table>
<thead>
<tr>
<th>Current Status</th>
<th>Revised Status</th>
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<tbody>
<tr>
<td>1A</td>
<td>1</td>
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<td>3</td>
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<td>1B</td>
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<td></td>
<td>5</td>
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<td>2</td>
<td>6</td>
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</tbody>
</table>

Current UNOS Adult Heart Allocation Criteria for Medical Urgency Status

**Status 1A**
Requires admission to listing transplant center and to have at least one of the following indications, devices, or therapies in place:
- Acute hemodynamic instability requiring mechanical circulatory support. This may include:
  - TAH
  - IABP
  - ECMO
  - Patients with LVAD and/or RVAD are afforded 30 days at any point after implementation if deemed clinically stable
- Patients with significant device-related complications while receiving mechanical circulatory support
- Continuous mechanical ventilation
- Continuous hemodynamic monitoring while receiving continuous infusion of a single high-dose or multiple intravenous inotropes

**Status 1B**
Requires at least one of the following devices or therapies in place:
- LVAD
- RVAD
- BiVAD
- Continuous infusion of intravenous inotropes

**Status 2**
- Transplant candidates who do not meet criteria for Status 1A or 1B

**Status 7**
- Transplant candidates who are deemed temporarily unsuitable to receive a heart transplant

Source: https://www.ncbi.nlm.nih.gov/pubmed/29409980
# New UNOS Adult Heart Allocation Criteria for Medical Urgency Status Effective September 2018

| Status 1 | • VA ECMO (7-day limit)
• Non-dischargeable, surgically implanted, non-endovascular biventricular support device
• MCS device with life-threatening ventricular arrhythmia |
| --- | --- |
| Status 2 | • TAH, BiVAD, RVAD or VAD for single ventricle patients
• Non-dischargeable, surgically implanted, non-endovascular LVAD (14-day limit)
• IABP (14-day limit)
• V-tach / V-fib, mechanical support not required
• MCS device with device malfunction/mechanical failure
• Percutaneous endovascular MCS device (14-day limit) |
| Status 3 | • Dischargeable LVAD for discretionary 30 days
• Multiple inotropes or a single high-dose inotrope with continuous hemodynamic monitoring
• VA ECMO after 7 days; percutaneous endovascular circulatory support device or IABP after 14 days
• Non-dischargeable, surgically implanted, non-endovascular LVAD after 14 days
• MCS device with one of the following:
  • device infection
  • hemolysis
  • pump thrombosis
  • right heart failure
  • mucosal bleeding
  • aortic insufficiency |
| Status 4 | • Dischargeable LVAD without discretionary 30 days
• Inotropes without hemodynamic monitoring
• Retransplant
• Diagnosis of one of the following:
  • congenital heart disease (CHD)
  • ischemic heart disease with intractable angina
  • hypertrophic cardiomyopathy
  • restrictive cardiomyopathy
  • amyloidosis |
| Status 5 | • On the waitlist for at least one other organ at the same hospital |
| Status 6 | • All remaining active candidates |

Source: https://optn.transplant.hrsa.gov/media/2414/adult_heart_infographic.pdf
# Key Changes

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<thead>
<tr>
<th>Device</th>
<th>Current</th>
<th>Revised</th>
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</thead>
<tbody>
<tr>
<td>TAH, In-hospital</td>
<td>Status 1A</td>
<td>Status 2</td>
</tr>
<tr>
<td>TAH, Discharged</td>
<td>Status 1B</td>
<td>Status 2</td>
</tr>
<tr>
<td>BiVAD, Discretionary 30 Days</td>
<td>Status 1A</td>
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<tr>
<td>BiVAD</td>
<td>Status 1B</td>
<td>Status 2</td>
</tr>
<tr>
<td>LVAD with Complications</td>
<td>Status 1A</td>
<td>Status 2</td>
</tr>
<tr>
<td>LVAD, Discretionary 30 Days</td>
<td>Status 1A</td>
<td>Status 2</td>
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<tr>
<td>LVAD</td>
<td>Status 1B</td>
<td>Status 2</td>
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<td>Congenital Heart Disease</td>
<td>Status 1B</td>
<td>Status 2</td>
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<tr>
<td>Ischemic Heart Disease</td>
<td>Status 1B</td>
<td>Status 2</td>
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<tr>
<td>Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy</td>
<td>Status 1B</td>
<td>Status 2</td>
</tr>
<tr>
<td>Re-Transplant</td>
<td>Status 1B</td>
<td>Status 2</td>
</tr>
</tbody>
</table>

Note: For a list of device brands by category, please see chart on page 8.
Key Takeaways

TAH Patients

Currently, TAH patients are listed Status 1A while in the hospital, then Status 1B after they’ve been discharged using the Freedom® Portable Driver. Under the new system, TAH patients will be classified as Status 2 and remain Status 2 for as long as they are supported by the device, regardless of their discharge status.

Discharge is important to TAH patients from a quality-of-life perspective, so this change represents a significant improvement for TAH patients. It’s also important to note that the TAH will be the only approved, dischargeable MCS device in Status 2 as there is no approved, dischargeable BiVAD or RVAD currently available.

LVAD Patients

The current allocation system lists LVAD patients as Status 1B with a discretionary 30 days at Status 1A. This priority listing reflects the reliability and performance of LVADs at the time of the system’s last revision; however, advances have since led to improved long-term outcomes in patients with advanced heart failure awaiting transplantation. UNOS has amended its criteria for LVADs accordingly. Under the new system, all discharged LVAD patients will be Status 4 with a discretionary 30 days at Status 3. LVAD patients experiencing complications, such as pump thrombus or device infection, will be listed as Status 3.

The downgrade in status for LVAD patients will likely make it more difficult for them to be transplanted, particularly after the discretionary 30 days at Status 3 have been used.

ECMO Patients

Under the current system, VA ECMO patients are Status 1A indefinitely. When the new system goes into effect, VA ECMO patients will be Status 1 for 7 days before dropping to Status 3.

A candidate’s status can only be extended beyond 7 days if the transplant program can provide objective evidence to the regional review board (RRB) of both of the following:

1. The candidate has demonstrated a contraindication to durable device support
2. Within 48 hours prior to the status expiring, the transplant program was unable to wean the candidate from VA ECMO, as evidenced by at least one of the following criteria:
   • Mean arterial pressure (MAP) less than 60 mmHg
   • Cardiac index less than 2.0 L/min/m²
   • Pulmonary capillary wedge pressure greater than 15 mmHg
   • SvO₂ less than 50% measured by central venous catheter

This change may pressure hospitals to make treatment decisions regarding bridge to candidacy or bridge to transplant much more quickly, because chances of receiving a donor heart directly from ECMO will drop substantially after 7 days.
Patients with Specific Etiologies

Under the new system, congenital heart disease, ischemic heart disease with intractable angina, amyloidosis, restrictive and hypertrophic cardiomyopathy and re-transplant patients will be Status 4.

When these patients inevitably begin to deteriorate on the transplant list, it will be critical that transplant centers select the appropriate treatment strategy and MCS device to both optimize their patients’ health and their chances of receiving a heart transplant.

Per the 2013 ISHLT guidelines, left ventricle (LV) support for patients with amyloidosis or restrictive or hypertrophic cardiomyopathy should be considered with caution. Because these conditions often affect both the left and right ventricles, LV support alone may be inadequate, and biventricular support or a TAH may be required. In addition, graft failure in heart transplant recipients often manifests as biventricular dysfunction, and use of LVADs as a bridge to transplant in this population has had limited success and has been associated with poor outcomes.


If you have questions, comments or concerns about the upcoming UNOS changes, or would just like to discuss the topic further, please contact your SynCardia Sales Representative or Clinical Specialist.

CAUTION – In the United States, the SynCardia 50cc TAH is an investigational device, limited by federal law to investigational use.
# Additional Resources

## Device Brands by Category

<table>
<thead>
<tr>
<th>TAH</th>
<th>Dischargeable VADs</th>
<th>Non Dischargeable VADs</th>
<th>Percutaneous Devices</th>
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<td>Heartsaver VAD</td>
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<td>Ventracor VentrAssist</td>
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Source: https://optn.transplant.hrsa.gov/media/2457/heart_device_brand_background.pdf