

## *Notice of OPTN Policy Changes*

# Amend Status Extension Requirements in Adult Heart Allocation Policy

<b>Sponsoring Committee:</b>	Heart Transplantation Committee
<b>Policies Affected:</b>	<i>6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)</i> <i>6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device</i> <i>6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia</i> <i>6.1.C: Adult Heart Status 3 Requirements</i> <i>6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis</i> <i>6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure</i> <i>6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection</i> <i>6.1.C.xiii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia After 7 Days</i>
<b>Public Comment:</b>	August 3, 2021 – September 30, 2021
<b>Board Approved:</b>	December 6, 2021
<b>Effective Date:</b>	Pending implementation and notice to OPTN members

### **Purpose of Policy Changes**

Following implementation of the adult heart allocation policy modifications in October 2018, the heart transplant community has sought clarification of the requirements for extending a candidate's status assignment. Transplant programs have sought feedback about whether new information is required when documenting a candidate's medical condition if not explicitly stated in policy, and whether hospitalization is required for an extension if it was required for the initial status assignment.

The policy changes identified in this notice amend adult heart allocation requirements to address the identified issues. Other changes include providing additional qualifying information for assigning candidates to status 2 who are experiencing a mechanical circulatory support device with pump thrombosis, and permitting certain status 1 candidates an opportunity to transition to status 3 under specific circumstances.

## Proposal History

The OPTN revised adult heart allocation policy most recently in 2020. The intent of those changes was to more closely align policy with clinical practice. While developing those policy changes in 2019 and 2020, the OPTN Heart Transplantation Committee (Committee) identified opportunities to clarify the conditions that must be met for a patient to remain at an assigned status beyond the first qualifying timeframe. The Committee also concluded that the transplant community would benefit from greater specificity about the criteria that must be met for a patient to qualify for a status extension. Finally, the Committee determined that clarifying the qualifying requirements associated with mechanical circulatory support with pump thrombosis was needed.

## Summary of Changes

The proposal continues the OPTN's efforts of improving upon the allocation policy changes implemented in October 2018. The changes address issues associated with adult heart status extension requirements by clarifying the circumstances by which a candidate must continue meeting qualifying criteria to be eligible for an extension of the status assignment. The changes also establish greater consistency in the status assignment timeframes for situations involving similar medical urgencies. The proposal includes the following changes:

- Clarifies that a candidate must be hospitalized for a transplant program to extend assignment under *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)*
- Clarifies that a candidate must continue meeting initial qualifying criteria for a transplant program to extend assignment under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device*
- Reduces the number of days from 14 to 7 that a candidate is eligible for assignment under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia*, and requires hospitalization for a transplant program to extend the assignment
- Revises *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis* to clarify which treatments and therapies should be associated with the status, and extends the number of days a transplant program can initially assign a candidate to from 14 to 30. In addition, the changes clarify that a candidate must continue meeting initial qualifying criteria for a transplant program to extend the assignment, and increases the extension timeframe from 14 to 90 days.
- Clarifies that a candidate must continue meeting initial qualifying criteria for a transplant program to extend assignment under *Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure* and increases the extension timeframe from 14 to 90 days.
- Modifies *Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection* by clarifying when the use of IV antibiotics is required, adding an option for recurrent debridement, and requiring a candidate to continue meeting initial qualifying criteria for a transplant program to extend the assignment
- Creates a new status 3 criterion for *Mechanical Circulatory Support Device (MCSD) with Life Threatening Arrhythmia After 7 Days* to transition candidates who no longer qualify for status 1 to an appropriate status

## Implementation

Adult heart transplant programs will need to educate personnel about the details associated with the policy modifications and the changes in the adult heart status justification and extension forms. Program

staff will also need to familiarize themselves with the revised qualifying criteria and permissible timeframes for status assignments.

The policy changes require IT system updates, and will go into effect following completion of the implementation in the system and notice to the community. Modifications are needed to several of the adult heart justification forms and the associated extension forms. In addition, changes related to the modified status timeframes are required. Professional education will prepare an educational offering addressing the changes for the heart transplantation community.

## Affected Policy Language

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

### 6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by VA ECMO for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to VA ECMO support, *all* of the following are true within one 24 hour period:
  - a. Systolic blood pressure less than 90 mmHg
  - b. Cardiac index less than 1.8 L/min/m<sup>2</sup> if the candidate is not supported by inotropes or less than 2.0 L/min/m<sup>2</sup> if the candidate is supported by at least one inotrope
  - c. Pulmonary capillary wedge pressure greater than 15 mmHg
- If hemodynamic measurements could not be obtained within 7 days prior to VA ECMO support, at least *one* of the following is true within 24 hours prior to VA ECMO support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet either of the criteria above will remain in this status for up to 7 days from submission of the *Heart Status 1 Justification Form*.

Every 7 days, the transplant program may apply to the regional review board (RRB) to extend the candidate at this status if the candidate remains hospitalized and is supported by VA ECMO. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from VA ECMO as evidenced by at least *one* of the following:
  - Mean arterial pressure (MAP) less than 60 mmHg
  - Cardiac index less than 2.0 L/min/m<sup>2</sup>
  - Pulmonary capillary wedge pressure greater than 15 mmHg
  - SvO<sub>2</sub> less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by VA ECMO after 7 days and either the extension request is not granted or the transplant

program does not request an extension, then the transplant program may assign the candidate to status 3.

#### **6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device**

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular biventricular support device and must remain hospitalized because the device is not FDA-approved for out of hospital use. This status is valid for up to 7 days from submission of *the Heart Status 1 Justification Form*.

~~This status can be extended by the transplant program every 7 days by submission of another *Heart Status 1 Justification Form*.~~ A candidate's transplant program may extend the candidate's status every 7 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 1 Justification Form*.

#### **6.1.A.iii Mechanical Circulatory Support Device (MCS) with Life Threatening Ventricular Arrhythmia**

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCS, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation as evidenced by at least *one* of the following:

- Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias
- That the patient was not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and has experienced three or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 14 7 days that *both*:
  1. Occurred in the setting of normal serum magnesium and potassium levels
  2. Required electrical cardioversion despite receiving continuous intravenous antiarrhythmic therapies

This status is valid for up to 14 7 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 14 7 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized on continuous intravenous antiarrhythmic therapy.

After 7 days, if the candidate remains hospitalized and the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

#### **6.1.C Adult Heart Status 3 Requirements**

To assign a candidate to adult status 3, the candidate's transplant program must submit a *Heart Status 3 Justification Form* to the OPTN. A candidate is not assigned adult status 3 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate adult status 3 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device and is exercising 30 days of discretionary time, according to *Policy 6.1.C.i* below.
- Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring, according to *Policy 6.1.C.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) with hemolysis, according to *Policy 6.1.C.iii* below.
- Is supported by an MCSD with pump thrombosis, according to *Policy 6.1.C.iv* below.
- Is supported by an MCSD and has right heart failure, according to *Policy 6.1.C.v* below.
- Is supported by an MCSD and has a device infection, according to *Policy 6.1.C.vi* below.
- Is supported by an MCSD and has bleeding, according to *Policy 6.1.C.vii* below.
- Is supported by an MCSD and has aortic insufficiency, according to *Policy 6.1.C.viii* below.
- Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days, according to *Policy 6.1.C.ix* below.
- Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) after 14 days, according to *Policy 6.1.C.x* below.
- Is supported by a percutaneous endovascular mechanical circulatory support device after 14 days, according to *Policy 6.1.C.xi* below.
- Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to *Policy 6.1.C.xii* below.
- Is supported by a MCSD and has life threatening ventricular arrhythmia after 7 days, according to *Policy 6.1.C.xiii* below.

#### **6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis**

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, and is experiencing pump thrombosis as evidenced by at least one of the following and the transplant program has identified a suspected pump thrombosis in either an implanted LVAD or a dischargeable paracorporeal device and both of the following criteria are met:

- ~~Visually detected thrombus in a paracorporeal ventricular assist device (VAD)~~
- ~~Transient ischemic attack, stroke, or peripheral thromboembolic event, with non-invasive testing to exclude both:~~
  - ~~1. Intracardiac thrombus in all candidates~~
  - ~~2. Significant carotid artery disease in candidates with a neurological event~~
- The candidate has one of the following conditions:
  - Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease,
  - A condition that requires inotropic support and presence of left-sided heart failure not explained by structural heart disease such as Aortic Insufficiency (AI) [as defined Policy 6.1.C.vii:MCSD with Mucosal Bleeding], as demonstrated by
    - Pulmonary Capillary Wedge Pressure (PCWP) greater than 15, and
    - Mean Arterial Pressure (MAP) less than 90
  - Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control
  - Visually detected thrombus in a paracorporeal ventricular device (VAD)
- The candidate is supported by one of the following treatments in the hospital:

- Intravenous anticoagulation (e.g. heparin)
- Intravenous thrombolytics (e.g. tPA)
- Intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban)

This status is valid for up to ~~14~~30 days from submission of *the Heart Status 3 Justification Form*.

~~After the initial 14~~30 days, ~~this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.~~ a candidate's transplant program may extend the candidate's status every 90 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 3 Justification Form*.

### **6.1.C.v Mechanical Circulatory Support Device (MCS D) with Right Heart Failure**

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCS D and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and *both* of the following:

1. Has been treated with at least one of the following therapies for at least 14 consecutive days, and requires ongoing treatment with at least *one* of the following therapies:
  - Dobutamine greater than or equal to 5 mcg/kg/min
  - Dopamine greater than or equal to 4 mcg/kg/min
  - Epinephrine greater than or equal to 0.05 mcg/kg/min
  - Inhaled nitric oxide
  - Intravenous prostacyclin
  - Milrinone greater than or equal to 0.35 mcg/kg/min
2. Has, within 7 days prior to initiation of any of the therapies above, pulmonary capillary wedge pressure less than 20 mmHg and central venous pressure greater than 18 mmHg within one 24 hour period.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*.

~~After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.~~ a candidate's transplant program may extend the candidate's status every 90 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 3 Justification Form*.

### **6.1.C.vi Mechanical Circulatory Support Device (MCS D) with Device Infection**

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCS D and is experiencing a pump-related local or systemic infection, with *at least one* of the symptoms according to *Table 6-1: Evidence of Device Infection* below.

**Table 6-1: Evidence of Device Infection**

If the candidate has evidence of:	Then this status is valid for up to:
<p>Erythema and pain along the driveline, <del>with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count,</del> <u>requiring IV antibiotics and either:</u></p> <ul style="list-style-type: none"> <li>• Positive bacterial or fungal cultures from the driveline exit site within the last 14 days</li> <li>• A culture-positive fluid collection between the driveline exit site and the device</li> </ul>	<p>14 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p>Debridement of the driveline with positive cultures from sites between the driveline exit site and the device <u>requiring IV antibiotics</u></p>	<p>14 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p><u>Recurrent debridement</u></p>	<p><u>90 days from submission of <i>the Heart Status 3 Justification Form</i>.</u></p>
<p>Positive culture of material from the pump pocket of an implanted device</p>	<p>90 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p>Bacteremia treated with antibiotics</p>	<p>42 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p>Recurrent bacteremia that recurs from the same organism within four weeks of completing antibiotic treatment to which the bacteria is susceptible</p>	<p>90 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form* a candidate's transplant program may extend the candidate's stay according to the time periods established in Table 6-1: Evidence of Device Infection if the candidate continues to meet the above criteria or the candidate continues to require intravenous (IV) antibiotics, and the transplant program submits another *Heart Status 3 Justification Form*.

**6.1.C.xiii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia After 7 Days**

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias or receiving continuous intravenous antiarrhythmic therapy, and has already been assigned to status 1 according to *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia* for 7 days. This status is valid for up to 7 days from submission of *the Heart Status 3 Justification Form*.

A candidate's transplant program may extend the candidate's status every 7 days if the candidate continues to meet the above criteria and the transplant program submits another Heart Status 3 Justification Form.

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