OPTN/UNOS Policy Notice Clarifications to the Adult Heart Allocation System Policy Language

Sponsoring Committee:	**Thoracic Organ Transplantation**
Policy/Bylaws Affected:	**6.1.A.i (Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)), 6.1.A.iii (Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia), 6.1.B.i (Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)), 6.1.B.iv (Percutaneous Endovascular Mechanical Circulatory Support Device), 6.1.B.v (Intra-Aortic Balloon Pump (IABP)), 6.1.C (Adult Heart Status 3 Requirements), 6.1.C.ii (Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring), 6.1.C.iii (Mechanical Circulatory Support Device (MCSD) with Hemolysis), 6.1.C.vii (Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding), 6.1.C.ix (VA ECMO after 14 Days)**
Effective Date:	**Pending Implementation and Notice to Members**

Problem Statement

The OPTN/UNOS Board of Directors approved changes to the adult heart allocation system on December 6, 2016. During the implementation of these policy changes, UNOS staff identified clarifications that are needed before the policy changes are fully implemented in 2018. The scope of these clarifications include inadvertent omissions and policy language changes necessary to provide clarity for programming or compliance monitoring.

Summary of Changes

The clarifications add language that was inadvertently omitted and includes the necessary specificity to criteria for programming or monitoring purposes. These changes will also add clarity regarding the member requirements.

These inadvertent omissions are addressed in this updated language:

- The coinciding status 3 criterion for *Policy 6.1.B.i (Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)*) was mistakenly omitted, so members would be unable to assign their candidate to this status criterion unless corrected. This criterion also was omitted from the status 3 section preamble and has been included in these updates.
- The original and modified proposals included a 14 day qualifying period for the VA ECMO criteria; but based on feedback from both rounds of public comment, the Committee ultimately proposed limiting the initial qualifying period for candidates supported by VA ECMO to 7 days. While this

change was made to the status 1 criterion, the change was inadvertently not carried over in the corresponding status 3 criterion, and is now included in this corrected policy.

Several sections in the originally approved policy language were clarified with additional specificity to enhance programming and monitoring of the policy:

- A clarification was necessary for all of the criteria that require RRB approval to extend at that status; the approved language was changed from "after*"* 14 (or 7, if VA ECMO) days to "every" 14 days because the transplant program may apply for an extension not once after the initial 14 days, but also every 14 days after.
- Part of the qualifying extension criteria for certain criteria states within 48 hours prior to the extension request to the RRB, the transplant program must show evidence of a failed weaning attempt. The intent was for programs to exhibit the candidate failed to wean within 48 hours of the status expiring, not 48 hours from the time they actually request an extension, which could be 4 days before the status actually expires. Therefore, the language was changed to clarify when programs should be showing evidence of a failed weaning attempt.
- *Policy 6.1.C.ii (Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring)* was corrected to make this requirement more liberal by changing "*the* qualifying inotrope therapy" to "*a* qualifying inotrope therapy".
- Simple clarifications needed to be made to *Policy 6.1.C.iii (Mechanical Circulatory Support Device (MCSD) with Hemolysis)*. The word "blood" was deleted from this language and the word "measured" was replaced with "collected". One of the sub-criterion options under this requirement was also clarified to specify that the results of the LDH test should be from a blood test by adding the word "blood".
- In *Policy 6.1.C.vii (Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding)*, Table 6-2 was changed to specify that the hospitalization has to have been for mucosal bleeding, consistent with the policy title.
- Finally, in *Policy 6.1.A.iii (Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia)*, one of the sub-criteria under the qualifying criteria for this status states the candidate "required electrical cardioversion despite receiving antiarrhythmic therapies." The addition of "continuous intravenous" to this sub-criterion and the extension language creates clarity and consistency in this section.

What Members Need to Do

These clarifications will not impact how OPTN members will implement the heart allocation policy changes approved by the OPTN Board of Directors in December 2016. Members should familiarize themselves with these changes, as well as the December 2016 Board-approved changes.

Affected Policy Language

New language is underlined (<u>example</u>) 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^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 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*. ~~After~~ 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 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 ~~extension request~~ 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^2
   - Pulmonary capillary wedge pressure greater than 15 mmHg
   - SvO_2 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.iii Mechanical Circulatory Support Device (MCSD) 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 MCSD, 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 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 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 14

days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized on continuous intravenous ~~anti-arrhythmic~~ antiarrhythmic therapy.

6.1.B.i Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)

A candidate's transplant program may assign a candidate to adult status 2 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 LVAD, and must remain hospitalized because the device is not FDA-approved for out of hospital use.

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. ~~After~~ Every 14 days, the transplant program may apply to the RRB to extend the candidate's registration if the candidate remains supported by the non-dischargeable surgically implanted, non-endovascular LVAD. 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 ~~extension request~~ status expiring, the transplant program failed at weaning the candidate from the non-dischargeable surgically implanted, non-endovascular LVAD 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^2
    - Pulmonary capillary wedge pressure greater than15
    - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the non-dischargeable surgically implanted, non-endovascular LVAD after 14 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.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by a percutaneous endovascular mechanical circulatory support device without an oxygenator for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to percutaneous endovascular mechanical circulatory 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^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 if the candidate is supported by inotropes
    c. Pulmonary capillary wedge pressure greater than 15 mmHg
- If hemodynamic measurements could not be obtained within 7 days prior to percutaneous endovascular mechanical support, at least *one* of the following is true within 24 hours prior to percutaneous endovascular mechanical circulatory 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 the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. ~~After~~ Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the percutaneous endovascular circulatory support device. 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 ~~extension request~~ status expiring, the transplant program failed at weaning the candidate from the acute percutaneous endovascular circulatory support device 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^2
   - Pulmonary capillary wedge pressure greater than15 mmHg
   - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the percutaneous endovascular mechanical circulatory support device after 14 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.B.v Intra-Aortic Balloon Pump (IABP)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by an IABP for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to IABP 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^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 if the candidate is supported by inotropes
  c. Pulmonary capillary wedge pressure greater than 15 mmHg
- If hemodynamic measurements could not be obtained within 7 days prior to IABP support, at least *one* of the following is true within 24 hours prior to IABP support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - AST or ALT greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. ~~After~~ Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the IABP. 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 ~~extension request~~ status expiring, the transplant program failed to wean the candidate from the IABP 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/m2
   - Pulmonary capillary wedge pressure greater than 15 mmHg
   - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the IABP after 14 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.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 Contractor. 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 ~~14~~ 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*
- Is supported by a percutaneous endovascular 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.*

6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the hospital that registered the candidate on the waiting list, and within 7 days prior to inotrope administration or while on inotropes meets *all* of the following:

1. Has *one* of the following:

- Invasive pulmonary artery catheter
- Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures

2. Is in cardiogenic shock, as evidenced by *all* of the following within one 24 hour period:
   a. Systolic blood pressure less than 90 mmHg
   b. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
   c. Cardiac index of *either*:
      - Less than 1.8 L/min/m^2 for candidates without inotropic or mechanical support within 7 days prior to inotrope administration
      - Less than 2.2 L/min/m^2 for candidates with inotropic or mechanical support
3. Is supported by *one* of the following:
   - A continuous infusion of *at least one* high-dose intravenous inotrope:
     - Dobutamine greater than or equal to 7.5 mcg/kg/min
     - Milrinone greater than or equal to 0.50 mcg/kg/min
     - Epinephrine greater than or equal to 0.02 mcg/kg/min
   - A continuous infusion of *at least two* intravenous inotropes:
     - Dobutamine greater than or equal to 3 mcg/kg/min
     - Milrinone greater than or equal to 0.25 mcg/kg/min
     - Epinephrine greater than or equal to 0.01 mcg/kg/min
     - Dopamine greater than or equal to 3 mcg/kg/min

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* if the candidate remains admitted to the hospital that registered the candidate on the waiting list, and the candidate remains supported by ongoing use of ~~the~~ a qualifying inotrope therapy and meets *all* of the following:

1. O*ne* of the following hemodynamic monitoring:
   - Invasive pulmonary artery catheter
   - Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures
2. Within 48 hours prior to the ~~extension request~~ status expiring, must meet *either* of the following:
   - Cardiac index less than 2.2 L/min/m^2 on the current medical regimen
   - Failed attempt to wean the inotrope support documented by at least *one* of the following:
     - Cardiac index less than 2.2 L/min/m^2 during dose reduction
     - Increase in serum creatinine by 20 percent over the value immediately prior to, and within 24 hours of, inotrope dose reduction
     - Increase in arterial lactate to greater than 2.5 mmol/L
     - SvO_2 less than 50 percent measured by central venous catheter

6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by *both* of the following:

1. Two separate ~~blood~~ samples ~~measured~~ collected within 48 hours of each other confirming markers of active hemolysis as evidenced by *at least two* of the following criteria:

- Blood ~~L~~lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
- Plasma free hemoglobin greater than 20 mg/dL
- Hemoglobinuria

2. Documentation of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis

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*.

6.1.C.vii Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding

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, has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD, and meets the requirements according to *Table 6-2: Evidence of Mucosal Bleeding* below:

Table 6-2: Evidence of Mucosal Bleeding

If *all* of the following occurred:	Then this status is valid for *either*:
1. The candidate received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding 2. The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds 3. The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode	• Up to 14 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized for mucosal bleeding at least two times within the past six months • Up to 90 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized for mucosal bleeding at least three times within the past six months

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form*.

6.1.C.ix VA ECMO after ~~14~~ 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 VA ECMO, and has already assigned the candidate to status 1 according to *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* for ~~14~~ 7 days.

This status is valid for up to ~~14~~ 7 days from submission of *the Heart Status 3 Justification Form*. After the initial ~~14~~ 7 days, this status can be extended by the transplant program every ~~14~~ 7 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.x Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)

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 a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) and has already been assigned to status 2 according to *Policy 6.1.B.i: Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD).*

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*.

6.1.C.xi Percutaneous Endovascular Circulatory Support Device after 14 Days

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

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