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

Sponsoring Committee: Thoracic Organ Transplantation Committee
Policy/Bylaws Affected: 6.1 (Adult Status Assignments and Update Requirements), 6.1.B (Adult Heart Status 2 Requirements), 6.1.B.iii (Mechanical Circulatory Support Device (MCSD) with Malfunction), 6.1.B.iv (Percutaneous Endovascular Mechanical Circulatory Support Device), 6.1.C (Adult Heart Status 3 Requirements), 6.1.C.v (Mechanical Circulatory Support Device (MCSD) with Right Heart Failure), 6.1.C.vi (Mechanical Circulatory Support Device (MCSD) with Device Infection), 6.1.C.x (Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)), 6.1.C.xi (Percutaneous Endovascular Circulatory Support Device after 14 Days), 6.2 (Pediatric Status Assignments and Update Requirements), and 6.6.E (Allocation of Hearts from Donors Less Than 18 Years Old)
Public Comment: N/A
Board Approval Date: June 12, 2018
Effective Date: Pending implementation and notice to OPTN 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 required to ensure the proper allocation of hearts from pediatric donors, in addition to several minor language clarifications.

Summary of Changes

These changes update the allocation tables to correct mislabeled and missing classifications in *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old* and *Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old*. Further, Board-approved policy language will revert to originally proposed language for number 1 in *Policy 6.1.C.v: Mechanical Circulatory Support (MCSD) with Right Heart Failure* to clarify the requirements for meeting this criterion. The remaining changes are non-substantive clerical changes.

These clarifications will not impact how OPTN members will implement the heart allocation policy changes. Members should familiarize themselves with the changes in both the original proposal and the additional policy notice, accessible on the OPTN website.

Affected Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~).

6.1 Adult Status Assignments and Update Requirements

Each adult heart transplant candidate at least 18 years old at the time of registration is assigned a status that reflects the candidate's medical urgency for transplant. The candidate's transplant program must submit a heart status justification form to the OPTN Contractor to assign a candidate the status for which the candidate qualifies. Transplant programs must assign candidates on the waiting list that are not currently suitable for transplant to the inactive status.

~~If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must submit a new heart status justification form to the OPTN Contractor within 24 hours of the change in medical condition.~~

If a candidate's transplant program does not submit a heart status justification form or the status expires and the transplant program does not submit a new heart status justification form, the candidate is assigned to status 6, or status 5 if the candidate is registered for another organ.

When registering a candidate, the transplant program must submit to the OPTN Contractor *all* of the following clinical data:

- Hemodynamic assessment results
- Functional status or exercise testing results
- Heart failure severity or end organ function indicators
- Heart failure therapies
- Mechanical support
- Sensitization risk, including CPRA, peak PRA, and number of prior sternotomies
- Current diagnosis

These clinical data must be submitted every time the transplant program submits a justification form unless a test needed to obtain the data has not been performed since the last justification form was submitted. The transplant program must maintain source documentation for all laboratory values reported to the OPTN Contractor.

6.1.B   Adult Heart Status 2 Requirements

To assign a candidate adult status 2, the candidate's transplant program must submit a *Heart Status 2 Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 2 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 to adult status 2 if the candidate has at least *one* of the following conditions:

- Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), according to *Policy 6.1.B.i* below.

- Is supported by a total artificial heart (TAH), biventricular assist device (BiVAD), right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients, according to *Policy 6.1.B.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) that is malfunctioning, according to *Policy 6.1.B.iii* below.
- Is supported by a percutaneous endovascular <u>mechanical</u> circulatory support device, according to *Policy 6.1.B.iv* below.
- Is supported by an intra-aortic balloon pump (IABP), according to *Policy 6.1.B.v* below.
- Is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation according to *Policy 6.1.B.vi* below.

6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction

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 MCSD that is experiencing device malfunction as evidenced by *all* of the following:

1. Malfunction of at least one of the components of the MCSD
2. Malfunction cannot be fixed without an entire device replacement
3. Malfunction is currently causing inadequate <u>mechanical</u> circulatory support or places the candidate at imminent risk of device stoppage

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

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 <u>circulatory</u> support, at least *one* of the following is true within 24 hours prior to percutaneous endovascular mechanical circulatory support:
  o CPR was performed on the candidate
  o Systolic blood pressure less than 70 mmHg
  o Arterial lactate greater than 4 mmol/L
  o 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*. 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 <u>mechanical</u> 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 status expiring, the transplant program failed at weaning the candidate from the ~~acute~~ percutaneous endovascular <u>mechanical</u> 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.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 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 <u>mechanical</u> 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.v   Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

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

1. <u>Has been treated with at least *one* of the following therapies for at least 14 consecutive days, and</u> ~~R~~requires <u>ongoing</u> treatment with at least *one* of the following therapies<u>:</u> ~~for at least 14 consecutive days~~:
   - 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*.

6.1.C.vi   Mechanical Circulatory Support Device (MCSD) with Device Infection

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD 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:
Erythema and pain along the driveline, with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and *either*: • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the <u>driveline</u> exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the <u>driveline</u> exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Bacteremia treated with antibiotics	42 days from submission of *the Heart Status 3 Justification Form*.

If the candidate has evidence of:	Then this status is valid for up to:
Recurrent bacteremia that recurs from the same organism within four weeks <u>of completing</u> ~~following~~ antibiotic treatment to which the bacteria is susceptible	90 days from submission of *the Heart Status 3 Justification Form.*
Positive culture of material from the pump pocket of an implanted device	90 days from submission of *the Heart Status 3 Justification Form.*

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.x Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD) <u>after 14 days</u>

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)* <u>for 14 days</u>.

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 <u>Mechanical</u> Circulatory Support Device after 14 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 a percutaneous~,~ endovascular <u>mechanical</u> circulatory support device, and has already been assigned to status 2 according to *Policy 6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device* for 14 days.

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.*

6.2 Pediatric Status Assignments and Update Requirements

Heart candidates less than 18 years old at the time of registration may be assigned any of the following:

- Pediatric status 1A
- Pediatric status 1B
- Pediatric status 2
- Inactive status

A candidate registered on the waiting list before turning 18 years old remains eligible for pediatric status until the candidate has been removed from the waiting list.

If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must submit a new heart status justification form to the OPTN Contractor within 24 hours of the change in medical condition.

6.6.E   Allocation of Hearts from Donors Less Than 18 Years Old

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-8* below.

Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult status 1 and primary blood type match with the donor
4	OPO's DSA	Adult status 1 and secondary blood type match with the donor
5	OPO's DSA	Adult status 2 and primary blood type match with the donor
6	OPO's DSA	Adult status 2 and secondary blood type match with the donor
7	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor
8	OPO's DSA or Zone A	Pediatric status 1B and secondary blood type match with the donor
9	Zone A	Adult status 1 and primary blood type match with the donor
10	Zone A	Adult status 1 and secondary blood type match with the donor
11	Zone A	Adult status 2 and primary blood type match with the donor
12	Zone A	Adult status 2 and secondary blood type match with the donor
13	OPO's DSA	Adult status 3 and primary blood type match with the donor
14	OPO's DSA	Adult status 3 and secondary blood type match with the donor
15	OPO's DSA	Adult status 4 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
16	OPO's DSA	Adult status 4 and secondary blood type match with the donor
17	OPO's DSA	Adult status 5 and primary blood type match with the donor
18	OPO's DSA	Adult status 5 and secondary blood type match with the donor
19	Zone A	Adult status 3 and primary blood type match with the donor
20	Zone A	Adult status 3 and secondary blood type match with the donor
21	Zone A	Adult status 4 and primary blood type match with the donor
22	Zone A	Adult status 4 and secondary blood type match with the donor
23	Zone A	Adult status 5 and primary blood type match with the donor
24	Zone A	Adult Status 5 and secondary blood type match with the donor
25	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
26	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
27	OPO's DSA	Adult status 6 and primary blood type match with the donor
28	OPO's DSA	Adult status 6 and secondary blood type match with the donor
29	Zone B	Pediatric status 1A and primary blood type match with the donor
30	Zone B	Pediatric status 1A and secondary blood type match with the donor
31	Zone B	Adult status 1 and primary blood type match with the donor
32	Zone B	Adult status 1 and secondary blood type match with the donor
33	Zone B	Adult status 2 and primary blood type match with the donor
34	Zone B	Adult status 2 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
35	Zone B	Pediatric status 1B and primary blood type match with the donor
36	Zone B	Pediatric status 1B and secondary blood type match with the donor
37	Zone B	Adult status 3 and primary blood type match with the donor
38	Zone B	Adult status 3 and secondary blood type match with the donor
39	Zone B	Adult status 4 and primary blood type match with the donor
40	Zone B	Adult status 4 and secondary blood type match with the donor
41	Zone B	Adult status 5 and primary blood type match with the donor
42	Zone B	Adult status 5 and secondary blood type match with the donor
3943	OPO's DSA Zone A	Pediatric status 2 and primary blood type match with the donor
4044	OPO's DSA Zone A	Pediatric status 2 and secondary blood type match with the donor
4145	OPO's DSA Zone A	Adult status 6 and primary blood type match with the donor
4246	OPO's DSA Zone A	Adult status 6 and secondary blood type match with the donor
47	Zone B	Pediatric status 2 and primary blood type match with the donor
48	Zone B	Pediatric status 2 and secondary blood type match with the donor
49	Zone B	Adult status 6 and primary blood type match with the donor
50	Zone B	Adult status 6 and secondary blood type match with the donor
4351	Zone C	Pediatric status 1A and primary blood type match with the donor
4452	Zone C	Pediatric status 1A and secondary blood type match with the donor
4553	Zone C	Adult status 1 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
46<u>54</u>	Zone C	Adult status 1 and secondary blood type match with the donor
47<u>55</u>	Zone C	Adult status 2 and primary blood type match with the donor
48<u>56</u>	Zone C	Adult status 2 and secondary blood type match with the donor
49<u>57</u>	Zone C	Pediatric status 1B and primary blood type match with the donor
50<u>58</u>	Zone C	Pediatric status 1B and secondary blood type match with the donor
51<u>59</u>	Zone C	Adult status 3 and primary blood type match with the donor
52<u>60</u>	Zone C	Adult status 3 and secondary blood type match with the donor
53<u>61</u>	Zone C	Adult status 4 and primary blood type match with the donor
54<u>62</u>	Zone C	Adult status 4 and secondary blood type match with the donor
55<u>63</u>	Zone C	Adult status 5 and primary blood type match with the donor
56<u>64</u>	Zone C	Adult status 5 and secondary blood type match with the donor
57<u>65</u>	Zone C	Pediatric status 2 and primary blood type match with the donor
58<u>66</u>	Zone C	Pediatric status 2 and secondary blood type match with the donor
59<u>67</u>	Zone C	Adult status 6 and primary blood type match with the donor
60<u>68</u>	Zone C	Adult status 6 and secondary blood type match with the donor
61<u>69</u>	Zone D	Pediatric status 1A and primary blood type match with the donor
62<u>70</u>	Zone D	Pediatric status 1A and secondary blood type match with the donor
63<u>71</u>	Zone D	Adult status 1 and primary blood type match with the donor
64<u>72</u>	Zone D	Adult status 1 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
65~~73~~	Zone D	Adult status 2 and primary blood type match with the donor
66~~74~~	Zone D	Adult status 2 and secondary blood type match with the donor
67~~75~~	Zone D	Pediatric status 1B and primary blood type match with the donor
68~~76~~	Zone D	Pediatric status 1B and secondary blood type match with the donor
69~~77~~	Zone D	Adult status 3 and primary blood type match with the donor
70~~78~~	Zone D	Adult status 3 and secondary blood type match with the donor
71~~79~~	Zone D	Adult status 4 and primary blood type match with the donor
72~~80~~	Zone D	Adult status 4 and secondary blood type match with the donor
73~~81~~	Zone D	Adult status 5 and primary blood type match with the donor
74~~82~~	Zone D	Adult status 5 and secondary blood type match with the donor
75~~83~~	Zone D	Pediatric status 2 and primary blood type match with the donor
76~~84~~	Zone D	Pediatric status 2 and secondary blood type match with the donor
77~~85~~	Zone D	Adult status 6 and primary blood type match with the donor
78~~86~~	Zone D	Adult status 6 and secondary blood type match with the donor
79~~87~~	Zone E	Pediatric status 1A and primary blood type match with the donor
80~~88~~	Zone E	Pediatric status 1A and secondary blood type match with the donor
81~~89~~	Zone E	Adult status 1 and primary blood type match with the donor
82~~90~~	Zone E	Adult status 1 and secondary blood type match with the donor
83~~91~~	Zone E	Adult status 2 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
~~84~~92	Zone E	Adult status 2 and secondary blood type match with the donor
~~85~~93	Zone E	Pediatric status 1B and primary blood type match with the donor
~~86~~94	Zone E	Pediatric status 1B and secondary blood type match with the donor
~~87~~95	Zone E	Adult status 3 and primary blood type match with the donor
~~88~~96	Zone E	Adult status 3 and secondary blood type match with the donor
~~89~~97	Zone E	Adult status 4 and primary blood type match with the donor
~~90~~98	Zone E	Adult status 4 and secondary blood type match with the donor
~~91~~99	Zone E	Adult status 5 and primary blood type match with the donor
~~92~~100	Zone E	Adult status 5 and secondary blood type match with the donor
~~93~~101	Zone E	Pediatric status 2 and primary blood type match with the donor
~~94~~102	Zone E	Pediatric status 2 and secondary blood type match with the donor
~~95~~103	Zone E	Adult status 6 and primary blood type match with the donor
~~96~~104	Zone E	Adult status 6 and secondary blood type match with the donor

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