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Mini-Brief

Additional Clarifications to the Adult Heart Allocation System Policy Language

OPTN/UNOS Thoracic Organ Transplantation Committee

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Additional Clarifications to the Adult Heart Allocation System Policy Language

Affected Policies:	*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, Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*
Sponsoring Committee:	*Thoracic Organ Transplantation Committee*
Public Comment Period:	*n/a*
Board of Director's Date:	*June 11-12, 2018*

Executive Summary

The OPTN/UNOS Board of Directors approved changes to the adult heart allocation system on December 6, 2016.[1,2] 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 additional minor language clarifications. Specifically, 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, 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 sub-criterion 1 in *Policy 6.1.C.v: Mechanical Circulatory Support (MCSD) with Right Heart Failure* to align with Thoracic Committee intent. These clarifications will not create additional work for OPTN/UNOS members.

[1] OPTN/UNOS Board of Directors Meeting. *Executive Summary.* December 5-6, 2016, St. Louis, MO. Accessed June 27, 2017. https://optn.transplant.hrsa.gov/media/2038/board_executivSesummary_201612.pdf
[2] OPTN/UNOS Policy Notice. *Proposal to Modify the Adult Heart Allocation System.* Accessed June 27, 2017. https://optn.transplant.hrsa.gov/media/2028/thoracic_policynotice_201612.pdf

What problem will this proposal address?

The OPTN/UNOS Board of Directors approved changes to the adult heart allocation system on December 6, 2016.[3,4] 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 additional minor language clarifications. Specifically, these changes update the allocation tables to correct mislabeled and missing classifications in *Policy 6.6.E, 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 sub-criterion 1 in *Policy 6.1.C.v Mechanical Circulatory Support (MCSD) with Right Heart Failure* to align with Thoracic Committee intent.

Corrections to *Policy 6.6.E, Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old*

The Committee's intent in modifying the pediatric donor table with the adult heart allocation changes was to "leave pediatric donor heart allocation unchanged to the extent possible" but "to eliminate the negative impact on allocation to pediatric 1B recipients and to leave the current balance of geographic sharing within pediatrics unchanged."[5]

Staff has since identified that there are four mislabeled classifications, and eight missing classifications in *Policy 6.6.E, Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old*.

The table approved by the Board includes a column for classification number, a column for geography, and a column for status and blood type compatibility. Table 1, below, illustrates how the table is configured in the approved policy.

Table 1: Example of Pediatric Donor Allocation Table

Classification Column	Geography Column	Status/Blood Type Column
1	OPO's DSA or Zone A	Pediatric Status 1A and primary blood type with the donor

In the version of the table approved by the Board, Pediatric Status 2 candidates and Adult Status 6 candidates in the OPO's DSA appear twice. The second time these candidates appear, the geography column should be "Zone A" instead of "OPO's DSA."

Additionally, classifications for the following candidates for both primary and secondary blood type match with the donor are missing from the approved table:

- Pediatric status 2 candidates in Zone A
- Adult status 6 candidates in Zone A
- Adult status 4 candidates in Zone B
- Adult status 5 candidates in Zone B

The missing classifications should all be added into the table in the following order, after the classification for "Zone B Adult Status 3" and secondary blood type match with the donor:

- Adult status 4 primary blood type match with the donor in Zone B
- Adult status 4 secondary blood type match with the donor in Zone B
- Adult status 5 primary blood type match with the donor in Zone B
- Adult status 5 secondary blood type match with the donor in Zone B

[3] OPTN/UNOS Board of Directors Meeting. Executive Summary. December 5-6, 2016, St. Louis, MO. Accessed June 27, 2017. https://optn.transplant.hrsa.gov/media/2038/board_executivesummary_201612.pdf
[4] OPTN/UNOS Policy Notice. Proposal to Modify the Adult Heart Allocation System. Accessed June 27, 2017. https://optn.transplant.hrsa.gov/media/2028/thoracic_policynotice_201612.pdf
[5] OPTN/UNOS Briefing Paper. Proposal to Modify the Adult Heart Allocation System. Accessed October 27, 2017. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf

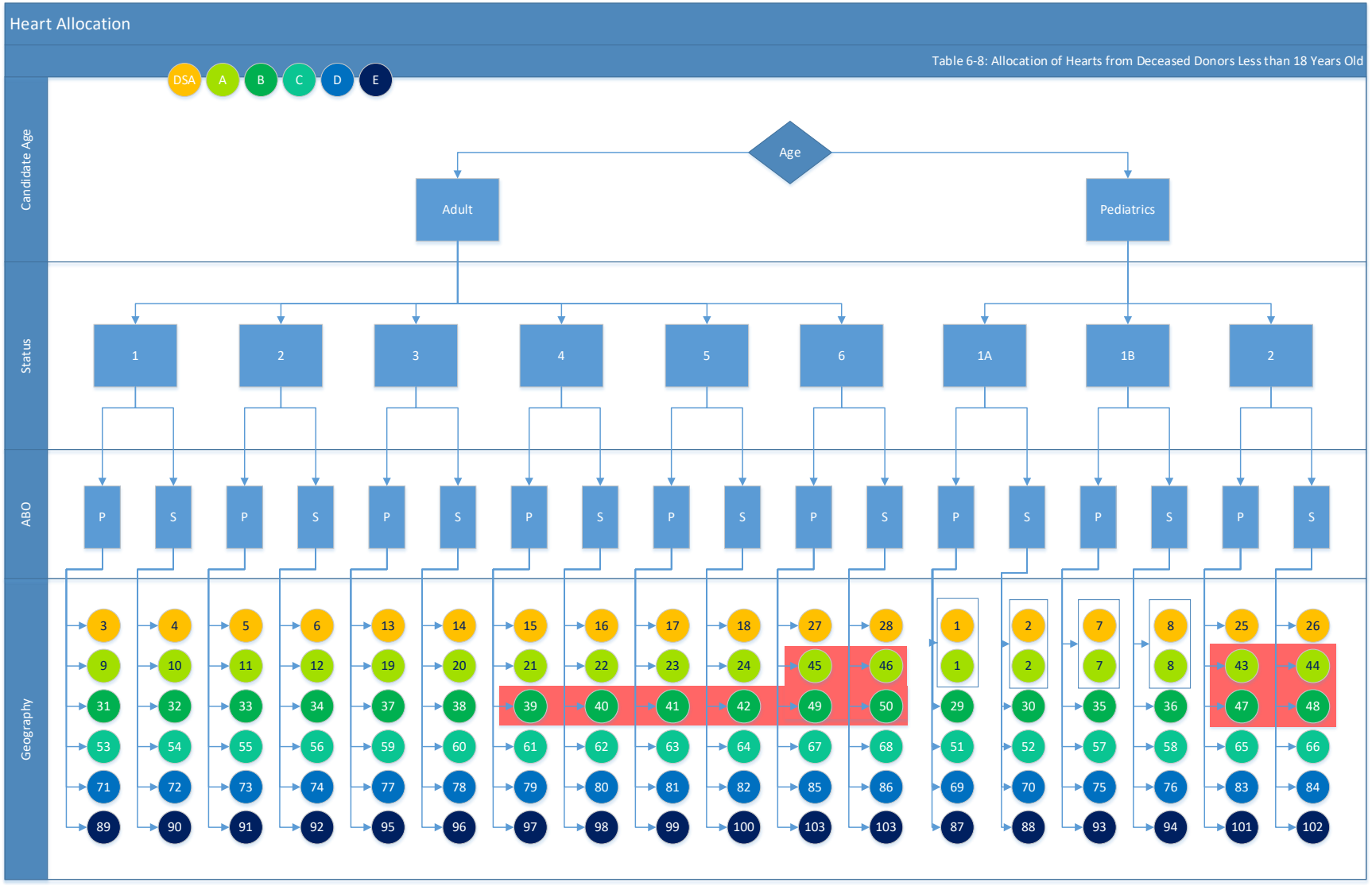
After the classification for “adult status 5 secondary blood type match with the donor in Zone B,” the table should be modified to remove the redundant classifications mentioned above to capture Zone A pediatric status 2 candidates and adult status 6 candidates. Immediately afterward, the remaining missing classifications should appear in the following order:

- Pediatric status 2 primary blood type match with the donor in Zone B
- Pediatric status 2 secondary blood type match with the donor in Zone B
- Adult status 6 primary blood type match with the donor in Zone B
- Adult status 6 secondary blood type match with the donor in Zone B

If the table is not changed, then these candidates will never appear on the match run for a pediatric donor heart, and therefore will not be able to receive offers from these donors.

Below is a graphical depiction of the heart allocation algorithm (**Figure 1**). The algorithm depicts their classification numbers with the proposed clarification. The impacted classifications are highlighted in red.

Figure 1: Heart Allocation Diagram



Clarifications to *Policy 6.1.C.v Mechanical Circulatory Support (MCSD) with Right Heart Failure*

Sub-criterion 1 under *Policy 6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure* evolved over two rounds of public comment and what ultimately went to the Board of Directors in December 2016 for approval. This criterion was adapted from the *Guidance Regarding Adult Heart Status 1A(b) Device-Related Complications*.[6] This criterion, developed by reviewing data from previous clinical trials, defined right failure as a candidate that has "at least moderate right ventricular (RV) dysfunction," and requiring either of the following treatments: at least two weeks of intravenous inotropes to support right heart function; or support of an RVAD with an ongoing requirement of physiologic evidence of clinical right heart failure based upon elevation of the central venous pressure, and need for intravenous inotropes. The Committee's intent was that a candidate required at least 14 consecutive days of intravenous inotropes, and still requires ongoing treatment of one of those therapies. **Table 2** demonstrates the evolution of this language.

Table 2: Evolution of Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

1st Round of Public Comment (January 2016)	2nd Round of Public Comment (August 2016)	Board of Directors (December 2016)
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 *all* of the following: **1. Has been treated for at least 14 days, and requires ongoing treatment with *at least one* of the following therapies…**	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 all of the following: **1. Requires treatment with at least one of the following therapies for at least 14 days…**	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. Requires treatment with at least one of the following therapies for at least 14 consecutive days…**

Policy language became less precise as it changed, and therefore, less consistent with the Committee's intent. Therefore, the Committee proposes merging the more specific language from the various iterations to better align with what they originally intended.

[6] Thoracic Organ Transplantation Committee. *Guidance Regarding Adult Heart Status 1A(b) Device-Related Complications,* 2013, Guidance, https://optn.transplant.hrsa.gov/resources/guidance/guidance-regarding-adult-heart-status-1a-b-device-related-complications/

Additional Clarifications

Finally, the Committee proposes the following clarifications:

Table 3: Proposed Clarifications

Policy	Clarification	Rationale
• *6.1 Adult Status Assignments and Update Requirements* • *6.2 Pediatric Status Assignments and Update Requirements*	Strike "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."	This exact language appears in section *6.3 Status Updates* and is redundant
• *6.1.B Adult Heart Status 2 Requirements preamble* • *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 preamble* • *6.1.C.xi Percutaneous Endovascular Mechanical Circulatory Support Device after 14 Days*	Insert "mechanical" where missing in phrase "mechanical circulatory support" or "mechanical circulatory support device"	Ensure consistency across heart policy language
• *6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device*	Insert "circulatory" where missing in phrase "mechanical circulatory support" or "mechanical circulatory support device"	Ensure consistency across heart policy language
• *6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection*	• 1st and 2nd sub-criteria: Insert "driveline" prior to "exit site" • 4th sub-criterion: Replace "following" with "of completing"	Ensure consistency across heart policy language and add specificity

The Committee approved the clarifications included herein and voted to recommend them to the Board of Directors for consideration in June, 2018.

Why should you support this proposal?

The proposed clarifications better align with the Committee's original intentions, including the order in which to allocate pediatric donor hearts. If these changes are not approved, there will be classes of candidates that do not have access to pediatric donor hearts because they will not show up on the match run, despite the Committee's intention to allocate pediatric donor hearts to all eligible candidates. Other clarifications will address inconsistent language and ambiguity.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* The proposed changes will ensure that all eligible candidates have access to pediatric donor hearts, in the order defined as equitable by the Committee when designing the adult heart allocation policy.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* These changes will permit the policy to be programmed as originally intended by the Committee and the Board. If these changes are not approved now, the policy will be programmed without these classifications, which would then compel the Committee to put forth effort on policy to fix these classifications, resulting in a future, additional programming effort and the associated costs.

How will the OPTN implement this proposal?

These clarifications will not impact how the OPTN will implement the heart allocation policy changes approved by the OPTN Board of Directors in December 2016.

An additional policy notice will be distributed to members to reflect the policy language.

How will members implement this proposal?

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 the changes in both the original proposal and the additional policy notice, accessible on the OPTN website.

Will this proposal require members to submit additional data?

No, these changes will not impact the additional risk stratification data collection approved as part of the heart allocation policy proposal.

How will members be evaluated for compliance with this proposal?

These policy language clarifications will not alter the routine monitoring of members. At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:

- Information reported on the adult status justification form is consistent with documentation in the candidate's medical record.
- The candidate met the requirements for the qualifying criterion selected on the adult status justification form and any required sub-criteria.
- The candidate's medical urgency status or qualifying criteria used to justify the status were updated in UNet^{SM} within 24 hours of a change in the candidate's medical condition to accurately reflect the change in condition.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

There are no changes to the adult heart allocation policy changes monitoring plan. These changes will be monitored in concert with the post-implementation monitoring of the heart allocation proposal. In monitoring the new allocation policy, the Committee will monitor pre- and post-transplant outcomes as well as access to transplant for specific sub-populations of transplant candidates six months for 2-3 years as the Committee sees fit.

Policy or Bylaws Language

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

RESOLVED, that changes to 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 Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old, as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

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 mechanical 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 mechanical 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 circulatory 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*. 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 mechanical 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 mechanical 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 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.*

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. Has been treated with at least *one* of the following therapies for at least 14 consecutive days, and ~~R~~requires ongoing treatment with at least *one* of the following therapies: ~~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 driveline 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 driveline 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*.
Recurrent bacteremia that recurs from the same organism within four weeks of completing ~~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) 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 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)* 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*.

6.1.C.xi Percutaneous Endovascular Mechanical 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 mechanical 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

Classification	Candidates that are within the:	And are:
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
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

Classification	Candidates that are within the:	And are:
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
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
~~39~~43	~~OPO's DSA~~ Zone A	Pediatric status 2 and primary blood type match with the donor
~~40~~44	~~OPO's DSA~~ Zone A	Pediatric status 2 and secondary blood type match with the donor
~~41~~45	~~OPO's DSA~~ Zone A	Adult status 6 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
~~42~~46	~~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
~~43~~51	Zone C	Pediatric status 1A and primary blood type match with the donor
~~44~~52	Zone C	Pediatric status 1A and secondary blood type match with the donor
~~45~~53	Zone C	Adult status 1 and primary blood type match with the donor
~~46~~54	Zone C	Adult status 1 and secondary blood type match with the donor
~~47~~55	Zone C	Adult status 2 and primary blood type match with the donor
~~48~~56	Zone C	Adult status 2 and secondary blood type match with the donor
~~49~~57	Zone C	Pediatric status 1B and primary blood type match with the donor
~~50~~58	Zone C	Pediatric status 1B and secondary blood type match with the donor
~~51~~59	Zone C	Adult status 3 and primary blood type match with the donor
~~52~~60	Zone C	Adult status 3 and secondary blood type match with the donor
~~53~~61	Zone C	Adult status 4 and primary blood type match with the donor
~~54~~62	Zone C	Adult status 4 and secondary blood type match with the donor
~~55~~63	Zone C	Adult status 5 and primary blood type match with the donor
~~56~~64	Zone C	Adult status 5 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
~~57~~65	Zone C	Pediatric status 2 and primary blood type match with the donor
~~58~~66	Zone C	Pediatric status 2 and secondary blood type match with the donor
~~59~~67	Zone C	Adult status 6 and primary blood type match with the donor
~~60~~68	Zone C	Adult status 6 and secondary blood type match with the donor
~~61~~69	Zone D	Pediatric status 1A and primary blood type match with the donor
~~62~~70	Zone D	Pediatric status 1A and secondary blood type match with the donor
~~63~~71	Zone D	Adult status 1 and primary blood type match with the donor
~~64~~72	Zone D	Adult status 1 and secondary blood type match with the donor
~~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

Classification	Candidates that are within the:	And are:
~~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
~~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

Classification	Candidates that are within the:	And are:
~~**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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