

OPTN/UNOS Policy Notice

Proposal to Modify the Adult Heart Allocation System

Sponsoring Committee:	Thoracic Organ Transplantation
Policy/Bylaws Affected:	Policies 3.7.B (Required Expedited Modifications of Waiting Time), 6.1 (Status Assignments and Update Requirements), 6.1.A (Adult Heart Status 1A Requirements), 6.1.B (Adult Heart Status 1B Requirements), 6.1.C (Adult Heart Status 2 Requirements), 6.2 (Status Updates), 6.3 (Adult and Pediatric Status Exceptions), 6.3.A (RRB and Committee Review of Exceptions), 6.3.B (Exceptions to Allocation for Sensitized Candidates), 6.4 (Waiting Time), 6.5.C (Sorting Within Each Classification), 6.5.D (Allocation of Hearts from Donors at Least 18 years Old), 6.5.E (Allocation of Hearts from Donors Less Than 18 Years Old), 6.5.F (Allocation of Heart-Lungs), Bylaws Appendix K.5 (Transition Plan during Long-term Inactivity, Termination, or Withdrawal), and Appendix M (Definitions)
Public Comment:	January and August, 2016
Effective Date:	Pending Implementation and notification to Members

Problem Statement

Since 2006, the number of active heart transplant candidates more than doubled. There are too many candidates with disparate urgency risks in the most urgent status. Some candidate groups are not served well by the current system and often must request exceptions. Medical practice in the heart transplant community has evolved since 2006; and the use of mechanical circulatory support devices (MCSDs) has increased significantly. Finally, the current geographic sharing scheme is inconsistent with the Final Rule since it favors less urgent candidates in the local DSA rather than more urgent candidates who may be as close as 25 miles away from the donor but are in Zone A.

Summary of Changes

- **Statuses:**
 - Transition from a three status system to a six status system
- **Broader sharing:**
 - Broader sharing for the most urgent statuses

What Members Need to Do

Implementation of this proposal will have the largest impact on transplant programs. You will be required to submit more data than is currently required for each of your candidates during each status change and at defined time intervals. You will need to add the required data for all your heart candidates registered on the waiting list before this policy is implemented. On the date of implementation, approved and pending exceptions will all be ineffective and if your patients do not meet the new policy criteria, you will be able to submit a new exception request. Importantly, your candidates will not lose waiting time during the transition.

Transplant programs should be aware that broader sharing may impact transplant program costs, as it may increase the number, distance, and time of additional heart fly outs and the resources (including donor recovery personnel and transplant program staff) required by your program.

Broader sharing may also impact OPO practices and costs.

Since the proposal requires programs to report cPRA data only if it is available (and does not mandate additional testing), it is unlikely that histocompatibility laboratories will experience increased testing costs.

Affected Policy Language:

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

1 **RESOLVED, that changes to Policies 3.7.B (Required Expedited Modifications of Waiting Time),**
 2 **6.1 (Status Assignments and Update Requirements), 6.1.A (Adult Heart Status 1A Requirements),**
 3 **6.1.B (Adult Heart Status 1B Requirements), 6.1.C (Adult Heart Status 2 Requirements), 6.2 (Status**
 4 **Updates), 6.3 (Adult and Pediatric Status Exceptions), 6.3.A (RRB and Committee Review of**
 5 **Exceptions), 6.3.B (Exceptions to Allocation for Sensitized Candidates), 6.4 (Waiting Time), 6.5.C**
 6 **(Sorting Within Each Classification), 6.5.D (Allocation of Hearts from Donors at Least 18 years**
 7 **Old), 6.5.E (Allocation of Hearts from Donors Less Than 18 Years Old), 6.5.F (Allocation of Heart-**
 8 **Lungs), Bylaws Appendix K.5 (Transition Plan during Long-term Inactivity, Termination, or**
 9 **Withdrawal), and Appendix M (Definitions), as set forth below, are hereby approved, effective**
 10 **pending implementation and notice to OPTN members.**

11 **3.7.B Required Expedited Modifications of Waiting Time**

12 An application for waiting time modifications must follow the procedures for expedited
 13 modifications of waiting time if it meets *any* of the following criteria according to *Table 3-5* below:
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Table 3-5: Applications Requiring Expedited Modifications of Waiting Time

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
An error occurred in removing the candidate's waiting list record	The same organ	Time accrued under the previous registration and any time lost by the error.
An error occurred in registering, modifying, or renewing the candidate's waiting list record	Status 1 liver, <u>pediatric</u> S status 1A heart, <u>adult status</u> <u>1, 2, 3, or 4 heart</u> , or P priority 1 pediatric lung	Any time lost by the error.

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
The candidate was removed from the waiting list for medical reasons, other than receiving a transplant	The same organ with the same diagnosis	Time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
An islet recipient has re-registered on the islet waiting list	An islet infusion	Any previously accrued waiting time according to <i>Policy 11.3.C: Islet Waiting Time Criteria</i> .
The candidate needs a second organ	Heart, liver, or lung	Modified waiting time for the second organ that includes the waiting time accrued for the first organ.
The candidate needs a second organ, routine alternative therapies are not possible, and the other transplant programs within the OPO and the OPO itself agree to the modified waiting time	Kidney, pancreas, or intestine	Modified waiting time for the second organ that includes the waiting time for the first organ.

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Additionally, applications must meet any additional requirements outlined in the organ-specific allocation policies. If an application does not comply with the requirements of *Policy 3.7: Waiting Time Modifications*, then the OPTN Contractor will not implement the requested waiting time modifications or forward the application for review.

Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, including the name and signature of the candidate's physician or surgeon, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ-specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

30 **6.1 Adult Status Assignments and Update Requirements**

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

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37 ~~Heart candidates at least 18 years old at the time of registration may be assigned any of the following:~~

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- 39 ● ~~Adult status 1A~~
- 40 ● ~~Adult status 1B~~
- 41 ● ~~Adult status 2~~
- 42 ● ~~Inactive status~~

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

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- 45 ● ~~Pediatric status 1A~~
- 46 ● ~~Pediatric status 1B~~
- 47 ● ~~Pediatric status 2~~
- 48 ● ~~Inactive status~~
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50 ~~A candidate registered on the waiting list before turning 18 years old remains eligible for pediatric status~~
51 ~~until the candidate has been removed from the waiting list.~~

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

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

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

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

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

74 **6.1.A Adult Heart Status 1A_1 Requirements**

75 To assign a candidate to adult status 1A, the candidate's transplant program must submit a
76 *Heart Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned to adult
77 status 1A until this form is submitted.

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79 If the candidate is at least 18 years old at the time of registration then the candidate's transplant
80 program may assign the candidate to adult status 1A if the candidate has at least *one* ~~either~~
81 of the following conditions ~~is met~~:

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- 83 ● Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO), according
84 to *Policy 6.1.A.i* below.
- 85 ● Is supported by a non-dischargeable, surgically implanted, non-endovascular biventricular
86 support device according to *Policy 6.1.A.ii* below.
- 87 ● Is supported by a mechanical circulatory support device (MCSD) and has a life-threatening
88 ventricular arrhythmia according to *6.1.A.iii* below.

89 **6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation**
90 **(VA ECMO)**

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

- 95 • Within 7 days prior to VA ECMO support, all of the following are true within one
96 24 hour period:
 - 97 a. Systolic blood pressure less than 90 mmHg
98 b. Cardiac index less than 1.8 L/min/m² if the candidate is not supported by
99 inotropes or less than 2.0 L/min/m² if the candidate is supported by at least
100 one inotrope
101 c. Pulmonary capillary wedge pressure greater than 15 mmHg
- 102 • If hemodynamic measurements could not be obtained within 7 days prior to VA
103 ECMO support, at least one of the following is true within 24 hours prior to VA
104 ECMO support:
 - 105 • CPR was performed on the candidate
106 • Systolic blood pressure less than 70 mmHg
- 107 •
- Arterial lactate greater than 4 mmol/L
- 108 •
- Aspartate transaminase (AST) or alanine transaminase (ALT) greater than
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- 1,000 U/L

110 Candidates that meet either of the criteria above will remain in this status for up to 7
111 days from submission of the Heart Status 1 Justification Form. After 7 days, the
112 transplant program may apply to the regional review board (RRB) to extend the
113 candidate at this status if the candidate remains supported by VA ECMO. The
114 transplant program must provide to the RRB objective evidence of both of the
115 following:

- 116 1. The candidate demonstrated a contraindication to being supported by a durable
117 device
- 118 2. Within 48 hours prior to the extension request, the transplant program failed at
119 weaning the candidate from VA ECMO as evidenced by at least one of the
120 following:
 - 121 • Mean arterial pressure (MAP) less than 60 mmHg
122 • Cardiac index less than 2.0 L/min/m²
123 • Pulmonary capillary wedge pressure greater than 15 mmHg124 • SvO₂ less than 50 percent measured by central venous catheter

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126 The RRB will retrospectively review extension requests. If the candidate is still
127 supported by VA ECMO after 7 days and either the extension request is not granted
128 or the transplant program does not request an extension, then the transplant program
129 may assign the candidate to status 3.

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131 **6.1.A.ii Non-dischargeable, Surgically Implanted, Non-**
132 **Endovascular Biventricular Support Device**

133 A candidate's transplant program may assign a candidate to adult status 1 if the
134 candidate is admitted to the transplant hospital that registered the candidate on the
135 waiting list, is supported by a surgically implanted, non-endovascular biventricular
136 support device and must remain hospitalized because the device is not FDA-
137 approved for out of hospital use.

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*.

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 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 intravenous anti-arrhythmic therapy.

1. ~~The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, or an affiliated Veteran's Administration (VA) hospital, and the candidate also meets at least *one* of the requirements in Table 6-1 below.~~

Table 6-1: Adult Status 1A Requirements for Candidates Currently Admitted to the Transplant Hospital

If the candidate meets this condition:	Then adult status 1A is valid for:
Has one of the following mechanical circulatory support devices in place: <ul style="list-style-type: none"> • Total artificial heart (TAH) • Intra-aortic balloon pump • Extracorporeal membrane oxygenation (ECMO) 	14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.
Requires continuous mechanical ventilation	14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the Status 1A registration.
Requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of left ventricular filling pressures. The OPTN Contractor will maintain a list of the OPTN-approved qualifying inotropes and doses.	7 days, and may be renewed for additional 7-day periods for each occurrence of an adult status 1A listing under this criterion for this candidate.

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2. A candidate who is at least 18 years old at the time of registration, and may or may not be currently admitted to the transplant hospital, may be assigned adult status 1A if the candidate meets at least one of the requirements in Table 6-2 below.

Table 6-2: Adult Status 1A Requirements for Candidates- Current Hospitalization Not Required

If the candidate meets this condition:	Then the status is valid for:
<p>Has one of the following mechanical circulatory support devices in place:</p> <ul style="list-style-type: none"> • Left ventricular assist device (LVAD) • Right ventricular assist device (RVAD) • Left and right ventricular assist devices (BiVAD) 	<p>30 days, and the candidate may be registered as adult status 1A for 30 days at any point after being implanted once an attending physician determines the candidate is medically stable. The 30 days do not have to be consecutive. However, if the candidate undergoes a procedure to receive another device, then the candidate qualifies for a new term of 30 days. Any 30 days granted by the new device would substitute and not supplement any time remaining from the previous adult status 1A classification.</p>
<p>Candidate has mechanical circulatory support and there is medical evidence of significant device-related complications including, but not limited to, thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias. A candidate's sensitization is not an acceptable device-related complication to qualify as adult status 1A. If a transplant program reports a complication that is not listed here, the registration will be retrospectively reviewed by the heart regional review board (RRB)</p>	<p>14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.</p>

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If the attending physician does not update the qualifications for adult status 1A registration when required according to Tables 6-1 and 6-2 above, then the candidate's adult status 1A will expire and the candidate will be downgraded to adult status 1B.

6.1.B Adult Heart Status 1B₂ Requirements

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To assign a candidate to adult status 2 ~~status 1B~~, the candidate's transplant program must submit a Heart Status 2 Status 1B Justification Form to the OPTN Contractor. A candidate is not assigned adult status 2 ~~status 1B~~ until this form is submitted.

The candidate's transplant program may assign the candidate as adult status 1B ~~if~~ 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 and has the candidate has at least one of the following devices or therapies in place 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 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.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 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, 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/m²
 - Pulmonary capillary wedge pressure greater than 15
 - SvO₂ 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.ii Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or Dischargeable Ventricular Assist Device (VAD) for Single Ventricle Patients

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is supported by *any* of the following:

- A TAH
- An RVAD alone
- A BiVAD
- A VAD, for single ventricle patients only

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*.

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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 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/m² if the candidate is not supported by inotropes or less than 2.0 L/min/m² 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 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, the transplant program failed at weaning the candidate from the acute percutaneous endovascular circulatory support device evidenced by at least one of the following:

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- Mean arterial pressure (MAP) less than 60 mmHg
- Cardiac index less than 2.0 L/min/m²
- Pulmonary capillary wedge pressure greater than 15 mmHg
- SvO₂ less than 50 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/m² if the candidate is not supported by inotropes or less than 2.0 L/min/m² 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 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, 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
 - SvO₂ 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.

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6.1.B.vi Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)

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 not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF episodes must have both of the following:

1. Occurred in the setting of normal serum magnesium and potassium levels
2. Required electrical cardioversion despite receiving intravenous antiarrhythmic therapies

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.

- ~~1. Left ventricular assist device (LVAD)~~
- ~~2. Right ventricular assist device (RVAD)~~
- ~~3. Left and right ventricular assist devices (BiVAD)~~
- ~~4. Continuous infusion of intravenous inotropes~~

~~Candidates that continue to qualify for adult status 1B may retain this status for an unlimited period and this status does not require any recertification, unless the candidate's medical condition changes as described in Policy 6.2: Status Updates.~~

6.1.C Adult Heart Status 2~~3~~ Requirements

~~If the candidate is at least 18 years old at the time of registration and does not meet the criteria for adult status 1A or 1B but is suitable for transplant, then the candidate may be assigned adult status 2.~~

~~The candidate may retain adult status 2 for an unlimited period and this status does not require recertification, unless the candidate's medical condition changes as described in Policy 6.2: Status Updates.~~

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 days, according to *Policy 6.1.C.ix* below.
- Is supported by a percutaneous endovascular circulatory support device after 14 days, according to *Policy 6.1.C.x* below.
- Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to *Policy 6.1.C.xi* below.

6.1.C.i Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by a dischargeable LVAD. OPTN Contractor maintains a list of OPTN-approved, qualifying devices.

The candidate may be registered as status 3 for 30 days at any point after being implanted with the dischargeable LVAD and once the attending physician determines the candidate is medically stable. Regardless of whether the candidate has a single transplant program registration or multiple transplant program registrations, the candidate receives a total of 30 days discretionary time for each dischargeable LVAD implanted across all registrations. Each day used by any of the transplant programs counts towards the cumulative 30 days.

The 30 days do not have to be consecutive and if the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.

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/m² for candidates without inotropic or mechanical support within 7 days prior to inotrope administration
 - Less than 2.2 L/min/m² 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:

- 452 ○ Dobutamine greater than or equal to 3 mcg/kg/min
- 453 ○ Milrinone greater than or equal to 0.25 mcg/kg/min
- 454 ○ Epinephrine greater than or equal to 0.01 mcg/kg/min
- 455 ○ Dopamine greater than or equal to 3 mcg/kg/min

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457 This status is valid for up to 14 days from submission of the Heart Status 3
458 Justification Form. After the initial 14 days, this status can be extended by the
459 transplant program every 14 days by submission of another Heart Status 3
460 Justification Form if the candidate remains admitted to the hospital that registered the
461 candidate on the waiting list, and the candidate remains supported by ongoing use of
462 the qualifying inotrope therapy and meets all of the following:

- 463 1. One of the following hemodynamic monitoring:
 - 464 • Invasive pulmonary artery catheter
 - 465 • Daily hemodynamic monitoring to measure cardiac output and left ventricular
 - 466 filling pressures
- 467 2. Within 48 hours prior to the extension request, must meet either of the following:
 - 468 • Cardiac index less than 2.2 L/min/m² on the current medical regimen
 - 469 • Failed attempt to wean the inotrope support documented by at least one of
 - 470 the following:
 - 471 ○ Cardiac index less than 2.2 L/min/m² during dose reduction
 - 472 ○ Increase in serum creatinine by 20 percent over the value immediately
 - 473 prior to, and within 24 hours of, inotrope dose reduction
 - 474 ○ Increase in arterial lactate to greater than 2.5 mmol/L
 - 475 ○ SvO₂ less than 50 percent measured by central venous catheter
 - 476

477 **6.1.C.iii Mechanical Circulatory Support Device (MCSD) with** 478 **Hemolysis**

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

- 482 1. Two separate blood samples measured within 48 hours of each other confirming
483 markers of active hemolysis as evidenced by at least two of the following criteria:
 - 484 • Lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at
 - 485 the laboratory reference range
 - 486 • Plasma free hemoglobin greater than 20 mg/dL
 - 487 • Hemoglobinuria
- 488 2. Documentation of at least one attempt to treat the condition using an intravenous
489 anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or
490 recurrent hemolysis
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492 This status is valid for up to 14 days from submission of the Heart Status 3
493 Justification Form. After the initial 14 days, this status can be extended by the
494 transplant program every 14 days by submission of another Heart Status 3
495 Justification Form.

496 **6.1.C.iv Mechanical Circulatory Support Device (MCSD) with** 497 **Pump Thrombosis**

498 A candidate's transplant program may assign a candidate to adult status 3 if the
499 candidate is supported by an MCSD and is experiencing pump thrombosis as
500 evidenced by at least one of the following:
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- 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

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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.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

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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:
 - 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.

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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

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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.

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Table 6-1: Evidence of Device Infection

<u>If the candidate has evidence of:</u>	<u>Then this status is valid for up to:</u>
<u>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:</u> <ul style="list-style-type: none"> • <u>Positive bacterial or fungal cultures from the driveline exit site within the last 14 days</u> • <u>A culture-positive fluid collection between the exit site and the device</u> 	<u>14 days from submission of the Heart Status 3 Justification Form.</u>
<u>Debridement of the driveline with positive cultures from sites between the exit site and the device</u>	<u>14 days from submission of the Heart Status 3 Justification Form.</u>
<u>Bacteremia treated with antibiotics</u>	<u>42 days from submission of the Heart Status 3 Justification Form.</u>
<u>Recurrent bacteremia that recurs from the same organism within four weeks following antibiotic treatment to which the bacteria is susceptible</u>	<u>90 days from submission of the Heart Status 3 Justification Form.</u>
<u>Positive culture of material from the pump pocket of an implanted device</u>	<u>90 days from submission of the Heart Status 3 Justification Form.</u>

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

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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

<u>If all of the following occurred:</u>	<u>Then this status is valid for either:</u>
<ol style="list-style-type: none"> 1. <u>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</u> 2. <u>The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds</u> 3. <u>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</u> 	<ul style="list-style-type: none"> • <u>Up to 14 days from submission of the <i>Heart Status 3 Justification Form</i>, if the candidate has been hospitalized for mucosal bleeding at least two times within the past six months</u> • <u>Up to 90 days from submission of the <i>Heart Status 3 Justification Form</i>, if the candidate has been hospitalized at least three times within the past six months</u>

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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.viii Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI)

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A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI, with all of the following:

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1. At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHg
2. Pulmonary capillary wedge pressure greater than 20 mmHg
3. New York Heart Association (NYHA) Class III-IV symptoms

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This status is valid for up to 90 days from submission of the *Heart Status 3 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 3 Justification Form*.

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6.1.C.ix VA ECMO after 14 Days

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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 days.

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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*.

589 **6.1.C.x Percutaneous Endovascular Circulatory Support Device**
590 **after 14 Days**

591 A candidate's transplant program may assign a candidate to adult status 3 if the
592 candidate is admitted to the transplant hospital that registered the candidate on the
593 waiting list, is supported by a percutaneous, endovascular circulatory support device,
594 and has already assigned the candidate to status 2 according to *Policy 6.1.B.iv:*
595 *Percutaneous Endovascular Mechanical Circulatory Support Device* for 14 days.

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

600
601 **6.1.C.xi Intra-Aortic Balloon Pump (IABP) after 14 Days**

602 A candidate's transplant program may assign a candidate to adult status 3 if the
603 candidate is admitted to the transplant hospital that registered the candidate on the
604 waiting list, is supported by an IABP, and has already assigned the candidate to
605 status 2 according to *Policy 6.1.B.v: Intra-Aortic Balloon Pump (IABP)* for 14 days.

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

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611 **6.1.D Adult Heart Status 4 Requirements**

612 To assign a candidate adult status 4, the candidate's transplant program must submit a *Heart*
613 *Status 4 Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 4
614 until this form is submitted.

615
616 If the candidate is at least 18 years old at the time of registration then the candidate's transplant
617 program may assign the candidate adult status 4 if the candidate has at least *one* of the following
618 conditions:

- 619
620
- 621 • Is supported by a dischargeable left ventricular assist device (LVAD), according to *Policy*
622 *6.1.D.i* below.
 - 623 • Is supported by inotropes without continuous hemodynamic monitoring, according to *Policy*
624 *6.1.D.ii* below.
 - 625 • Is diagnosed with congenital heart disease, according to *Policy 6.1.D.iii* below.
 - 626 • Is diagnosed with ischemic heart disease with intractable angina, according to *Policy 6.1.D.iv*
627 below.
 - 628 • Is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy,
629 according to *Policy 6.1.D.v* below.
 - 630 • Is a re-transplant, according to *Policy 6.1.D.vi* below.

631 **6.1.D.i Dischargeable Left Ventricular Assist Device (LVAD)**
632 **without Discretionary 30 Days**

633 A candidate's transplant program may assign a candidate to adult status 4 if the
634 candidate is supported by a dischargeable LVAD. The OPTN Contractor maintains a
635 list of OPTN-approved, qualifying devices.

636

637 This status is valid for up to 90 days from submission of the Heart Status 4
638 Justification Form. After the initial 90 days, this status can be extended by the
639 transplant program every 90 days by submission of another Heart Status 4
640 Justification Form.

641 **6.1.D.ii Inotropes without Hemodynamic Monitoring**

642 A candidate's transplant program may assign a candidate to adult status 4 if the
643 candidate is supported by a continuous infusion of a positive inotropic agent, and
644 meets all of the following:

- 645 1. Cardiac index of less than 2.2 L/min/m² within 7 days prior to submission of the
646 Heart Status 4 Status Justification Form
- 647 2. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
- 648 3. Requires at least one of the following intravenous inotropes:
 - 649 ○ Dobutamine greater than or equal to 3 mcg/kg/min
 - 650 ○ Milrinone greater than or equal to 0.25 mcg/kg/min
 - 651 ○ Epinephrine greater than or equal to 0.01 mcg/kg/min
 - 652 ○ Dopamine greater than or equal to 3 mcg/kg/min
 - 653 ○ Dopamine greater than or equal to 3 mcg/kg/min

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655 This status is valid for up to 90 days from submission of the Heart Status 4
656 Justification Form. After the initial 90 days, this status can be extended by the
657 transplant program every 90 days by submission of another Heart Status 4
658 Justification Form.

660 **6.1.D.iii Congenital Heart Disease**

661 A candidate's transplant program may assign a candidate to adult status 4 if the
662 candidate is diagnosed with a hemodynamically significant congenital heart disease.
663 The OPTN Contractor maintains a list of OPTN-approved qualifying congenital heart
664 disease diagnoses.

665
666 This status is valid for up to 90 days from submission of the Heart Status 4
667 Justification Form. After the initial 90 days, this status can be extended by the
668 transplant program every 90 days by submission of another Heart Status 4
669 Justification Form.

671 **6.1.D.iv Ischemic Heart Disease with Intractable Angina**

672 A candidate's transplant program may assign a candidate to adult status 4 if the
673 candidate is diagnosed with ischemic heart disease and has intractable angina, with
674 all of the following:

- 675 1. Coronary artery disease
- 676 2. Canadian Cardiovascular Society Grade IV angina pectoris that cannot be
677 treated by a combination of medical therapy, and percutaneous or surgical
678 revascularization
- 679 3. Myocardial ischemia shown by imaging

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682 This status is valid for up to 90 days from submission of the Heart Status 4
683 Justification Form. After the initial 90 days, this status can be extended by the
684 transplant program every 90 days by submission of another Heart Status 4
685 Justification Form.

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6.1.D.v Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, with at least one of the following:

- Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy
- New York Heart Association (NYHA) Class III-IV symptoms with either:
 - Cardiac index less than 2.2 L/min/m²
 - Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mmHg
- Ventricular tachycardia lasting at least 30 seconds
- Ventricular fibrillation
- Ventricular arrhythmia requiring electrical cardioversion
- Sudden cardiac death

This status is valid for up to 90 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.

6.1.D.vi Re-transplant

A candidate's transplant program may assign a candidate to adult status 4 if the candidate has a previous heart transplant, and there is evidence of International Society of Heart and Lung Transplantation (ISHLT) coronary allograft vasculopathy (CAV) grade 2-3, or New York Heart Association (NYHA) Class III-IV heart failure symptoms.

This status is valid for up to 90 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.

6.1.E Adult Heart Status 5 Requirements

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 5 if the candidate is registered on the heart waiting list, and is also registered on the waiting list for at least one other organ at the same hospital.

This status is valid for up to 180 days from submission of the Heart Status 5 Justification Form as long as the candidate is registered for another organ at the same hospital. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another Heart Status 5 Justification Form as long as the candidate is registered for another organ at the same hospital.

6.1.F Adult Heart Status 6 Requirements

If the candidate is at least 18 years old at the time of registration and is suitable for transplant, then the transplant program may assign the candidate to adult status 6.

736 This status is valid for up to 180 days from submission of the Heart Status 6 Justification Form as
 737 long as the candidate remains suitable for transplant. After the initial 180 days, this status can be
 738 extended by the transplant program every 180 days by submission of another Heart Status 6
 739 Justification Form as long as the candidate remains suitable for transplant.

741 **6.2 Pediatric Status Updates Assignments and Update**
 742 **Requirements**

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

- 745 • Pediatric status 1A
- 746 • Pediatric status 1B
- 747 • Pediatric status 2
- 748 • Inactive status

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

752
 753 If a candidate's medical condition changes and the criteria used to justify that candidate's status is no
 754 longer accurate, then the candidate's transplant program must submit a new heart status justification form
 755 to the OPTN Contractor within 24 hours of the change in medical condition.

757 **6.4.2DA Pediatric Heart Status 1A Requirements**

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

761 **6.3 Status-Adult and Pediatric Status Exceptions**

762 A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

763 **Table 6-3: Exception Qualification and Periods**

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 4A <u>status 1</u>	1. •-Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. •-Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested <u>status-status</u>	RRBs retrospectively review requests for <u>status 1Status 4A</u> -exceptions	14 days	<ul style="list-style-type: none"> • Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned adult status 4B

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
<p><u>Adult status 2</u> <u>status 4B</u></p>	<p>1. <u>Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</u></p> <p>2. <u>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</u></p>	<p>RRBs retrospectively review requests for <u>status 2</u> <u>Status 4B</u> exceptions</p>	<p><u>Indefinite</u> <u>14 days</u></p>	<ul style="list-style-type: none"> • <u>Not required as long as the candidate's medical condition remains the same.</u> • <u>Require RRB approval for each successive 14 day period</u> • <u>RRB will review and decide extension requests retrospectively</u>
<p><u>Adult status 3</u></p>	<p>1. <u>Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</u></p> <p>2. <u>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</u></p>	<p>RRBs retrospectively review requests for <u>status 3</u> exceptions</p>	<p><u>14 days</u></p>	<ul style="list-style-type: none"> • <u>Require RRB approval for each successive 14 day period</u> • <u>RRB will review and decide extension requests retrospectively</u>
<p><u>Adult status 4</u></p>	<p><u>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</u></p>	<p>RRBs retrospectively review requests for <u>status 4</u> exceptions</p>	<p><u>90 days</u></p>	<ul style="list-style-type: none"> • <u>Require RRB approval for each successive 90 day period</u> • <u>RRB will review and decide extension requests retrospectively</u>

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Pediatric status 1A	<ul style="list-style-type: none"> • Candidate is admitted to the transplant hospital that registered the candidate on the waiting list • Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status 	RRBs retrospectively review requests for Status 1A exceptions	14 days	<ul style="list-style-type: none"> • Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned pediatric status 1B
Pediatric status 1B	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for Status 1B exceptions	Indefinite	<ul style="list-style-type: none"> • Not required as long as candidate's medical condition remains the same

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The candidate's transplant physician must submit a justification form to the OPTN Contractor with the requested status and the rationale for granting the status exception.

6.3.A RRB and Committee Review of Status Exceptions

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The heart RRB reviews all applications for adult and pediatric status exceptions and extensions retrospectively. If an adult status 1A exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status. If a pediatric status 1A or status 1B exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status, subject to automatic review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may review the RRB's decisions and rationale, and may refer any case to the Membership and Professional Standards Committee (MPSC) for further review.

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If the candidate is transplanted and the RRB does not approve the initial exception or extension request or any appeal, then the case will be referred to the Thoracic Committee. If the Thoracic Committee agrees with the RRB's decision, then the Thoracic Committee may refer the case to Membership & Professional Standards Committee (MPSC) for review according to Appendix L of the OPTN Bylaws.

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6.3.A.i. RRB Appeals

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If the RRB denies an exception or extension request, the candidate's transplant program must either appeal to the RRB within 1 day of receiving notification of the

789 RRB denial, or assign the candidate to the status for which the candidate qualifies
790 within 1 day of receiving notification of the RRB denial.

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6.3.A.ii Committee Appeals

793 If the RRB denies the appeal, the candidate's transplant program must within 1 day
794 of receiving notification of the denied RRB appeal either appeal to the Thoracic
795 Organ Transplantation Committee or assign the candidate to the status for which the
796 candidate qualifies. If the Thoracic Committee agrees with the RRB's decision, the
797 candidate's transplant program must assign the candidate to the status for which the
798 candidate qualifies within 1 day of receiving notification of the denied Committee
799 appeal. If the transplant program does not assign the candidate to the status for
800 which the candidate qualifies within 1 day of receiving notification of the denied
801 Committee appeal, then the Committee will refer the case to the MPSC.

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6.3.B Exceptions to Allocation for Sensitized Patients

804 An OPO transplant program may allocate a heart to sensitized candidates within its DSA out of
805 sequence within a status as defined in *Policy 6.5: Heart Allocation Classifications and Rankings* if
806 all of the following are true:

807

- 808 1. The candidate's transplant surgeon or physician determines that the candidate's antibodies
809 would react adversely to certain human leukocyte antigens (HLA).
- 810 2. All heart transplant programs and the OPO within the DSA agree to allocate a heart from a
811 compatible deceased donor to the sensitized candidate.
- 812 3. The candidate's transplant program, all heart transplant programs, and the OPO within the
813 DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization
814 exception.

815

816 The sensitized candidate can only be prioritized ahead of candidates with the same status and
817 within the same DSA. Sensitization alone does not qualify a candidate to be assigned any status
818 exception as described in *Policy 6.3: Adult and Pediatric Status Exceptions* above.

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6.4 Waiting Time

821 Waiting time for heart candidates begins when the candidate is first registered as an active heart
822 candidate on the waiting list, and is calculated within each heart status.

823

824 If a candidate's status is upgraded, waiting time accrued while ~~registered at the~~ assigned to a lower status
825 is not transferred to the higher status. Conversely, waiting time accrued while ~~registered~~ assigned at a
826 higher status is transferred to a lower status if the candidate is ~~downgraded~~ assigned to a lower status.

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828 Waiting time does not accrue while the candidate is inactive.

829

6.5 Heart Allocation Classifications and Rankings

6.5.C Sorting Within Each Classification

832 Candidates are sorted within each classification by the total amount of waiting time that the
833 candidate has accumulated at that status, according to *Policy 6.4: Waiting Time*.

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6.5.D Allocation of Hearts from Donors at Least 18 years Old

836 Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table*
837 *6-7* below.

Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>1</u>	<u>OPO's DSA or Zone A</u>	<u>Adult status 1 or pediatric status 1A and primary blood type match with the donor</u>
<u>2</u>	<u>OPO's DSA or Zone A</u>	<u>Adult status 1 or pediatric status 1A and secondary blood type match with the donor</u>
<u>3</u>	<u>OPO's DSA or Zone A</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>4</u>	<u>OPO's DSA or Zone A</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>5</u>	<u>OPO's DSA</u>	<u>Adult status 3 or pediatric status 1B and primary blood type match with the donor</u>
<u>6</u>	<u>OPO's DSA</u>	<u>Adult status 3 or pediatric status 1B and secondary blood type match with the donor</u>
<u>7</u>	<u>Zone B</u>	<u>Adult status 1 or pediatric status 1A and primary blood type match with the donor</u>
<u>8</u>	<u>Zone B</u>	<u>Adult status 1 or pediatric status 1A and secondary blood type match with the donor</u>
<u>9</u>	<u>Zone B</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>10</u>	<u>Zone B</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>11</u>	<u>OPO's DSA</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>12</u>	<u>OPO's DSA</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>13</u>	<u>Zone A</u>	<u>Adult status 3 or pediatric status 1B and primary blood type match with the donor</u>
<u>14</u>	<u>Zone A</u>	<u>Adult status 3 or pediatric status 1B and secondary blood type match with the donor</u>
<u>15</u>	<u>OPO's DSA</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>16</u>	<u>OPO's DSA</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>17</u>	<u>Zone B</u>	<u>Adult status 3 or pediatric status 1B and primary blood type match with the donor</u>
<u>18</u>	<u>Zone B</u>	<u>Adult status 3 or pediatric status 1B and secondary blood type match with the donor</u>
<u>19</u>	<u>OPO's DSA</u>	<u>Adult status 6 or pediatric status 2 and primary blood type match with the donor</u>
<u>20</u>	<u>OPO's DSA</u>	<u>Adult status 6 and pediatric status 2 and secondary blood type match with the donor</u>
<u>21</u>	<u>Zone C</u>	<u>Adult status 1 or pediatric status 1A and primary blood type match with the donor</u>

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>22</u>	<u>Zone C</u>	<u>Adult status 1 or pediatric status 1A and secondary blood type match with the donor</u>
<u>23</u>	<u>Zone C</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>24</u>	<u>Zone C</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>25</u>	<u>Zone C</u>	<u>Adult status 3 or pediatric status 1B and primary blood type match with the donor</u>
<u>26</u>	<u>Zone C</u>	<u>Adult status 3 or pediatric status 1B and secondary blood type match with the donor</u>
<u>27</u>	<u>Zone A</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>28</u>	<u>Zone A</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>29</u>	<u>Zone A</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>30</u>	<u>Zone A</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>31</u>	<u>Zone A</u>	<u>Adult status 6 or pediatric status 2 and primary blood type match with the donor</u>
<u>32</u>	<u>Zone A</u>	<u>Adult status 6 or pediatric status 2 and secondary blood type match with the donor</u>
<u>33</u>	<u>Zone D</u>	<u>Adult status 1 or pediatric status 1A and primary blood type match with the donor</u>
<u>34</u>	<u>Zone D</u>	<u>Adult status 1 or pediatric status 1A and secondary blood type match with the donor</u>
<u>35</u>	<u>Zone D</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>36</u>	<u>Zone D</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>37</u>	<u>Zone D</u>	<u>Adult status 3 or pediatric status 1B and primary blood type match with the donor</u>
<u>38</u>	<u>Zone D</u>	<u>Adult status 3 or pediatric status 1B and secondary blood type match with the donor</u>
<u>39</u>	<u>Zone B</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>40</u>	<u>Zone B</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>41</u>	<u>Zone B</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>42</u>	<u>Zone B</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>43</u>	<u>Zone B</u>	<u>Adult status 6 or pediatric status 2 and primary blood type match with the donor</u>

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>44</u>	<u>Zone B</u>	<u>Adult status 6 or pediatric status 2 and secondary blood type match with the donor</u>
<u>45</u>	<u>Zone E</u>	<u>Adult status 1 or pediatric status 1A and primary blood type match with the donor</u>
<u>46</u>	<u>Zone E</u>	<u>Adult status 1 or pediatric status 1A and secondary blood type match with the donor</u>
<u>47</u>	<u>Zone E</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>48</u>	<u>Zone E</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>49</u>	<u>Zone E</u>	<u>Adult status 3 or pediatric status 1B and primary blood type match with the donor</u>
<u>50</u>	<u>Zone E</u>	<u>Adult status 3 or pediatric status 1B and secondary blood type match with the donor</u>
<u>51</u>	<u>Zone C</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>52</u>	<u>Zone C</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>53</u>	<u>Zone C</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>54</u>	<u>Zone C</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>55</u>	<u>Zone C</u>	<u>Adult status 6 or pediatric status 2 and primary blood type match with the donor</u>
<u>56</u>	<u>Zone C</u>	<u>Adult status 6 or pediatric status 2 and secondary blood type match with the donor</u>
<u>57</u>	<u>Zone D</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>58</u>	<u>Zone D</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>59</u>	<u>Zone D</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>60</u>	<u>Zone D</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>61</u>	<u>Zone D</u>	<u>Adult status 6 or pediatric status 2 and primary blood type match with the donor</u>
<u>62</u>	<u>Zone D</u>	<u>Adult status 6 or pediatric status 2 and secondary blood type match with the donor</u>
<u>63</u>	<u>Zone E</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>64</u>	<u>Zone E</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>65</u>	<u>Zone E</u>	<u>Adult status 5 and primary blood type match with the donor</u>

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>66</u>	<u>Zone E</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>67</u>	<u>Zone E</u>	<u>Adult status 6 or pediatric status 2 and primary blood type match with the donor</u>
<u>68</u>	<u>Zone E</u>	<u>Adult status 6 or pediatric status 2 and secondary blood type match with the donor</u>

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

Classification	Candidates that are within the:	And are:
18	Zone B	Adult or pediatric status 2 and secondary blood type match with the donor
19	Zone C	Adult or pediatric status 1A and primary blood type match with the donor
20	Zone C	Adult or pediatric status 1A and secondary blood type match with the donor
21	Zone C	Adult or pediatric status 1B and primary blood type match with the donor
22	Zone C	Adult or pediatric status 1B and secondary blood type match with the donor
23	Zone C	Adult or pediatric status 2 and primary blood type match with the donor
24	Zone C	Adult or pediatric status 2 and secondary blood type match with the donor
25	Zone D	Adult or pediatric status 1A and primary blood type match with the donor
26	Zone D	Adult or pediatric status 1A and secondary blood type match with the donor
27	Zone D	Adult or pediatric status 1B and primary blood type match with the donor
28	Zone D	Adult or pediatric status 1B and secondary blood type match with the donor
29	Zone D	Adult or pediatric status 2 and primary blood type match with the donor
30	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
31	Zone E	Adult or pediatric status 1A and primary blood type match with the donor
32	Zone E	Adult or pediatric status 1A and secondary blood type match with the donor
33	Zone E	Adult or pediatric status 1B and primary blood type match with the donor
34	Zone E	Adult or pediatric status 1B and secondary blood type match with the donor
35	Zone E	Adult or pediatric status 2 and primary blood type match with the donor
36	Zone E	Adult or pediatric status 2 and secondary blood type match with the donor

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6.5.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

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>1</u>	<u>OPO's DSA or Zone A</u>	<u>Pediatric status 1A and primary blood type match with the donor</u>
<u>2</u>	<u>OPO's DSA or Zone A</u>	<u>Pediatric status 1A and secondary blood type match with the donor</u>
<u>3</u>	<u>OPO's DSA</u>	<u>Adult status 1 and primary blood type match with the donor</u>
<u>4</u>	<u>OPO's DSA</u>	<u>Adult status 1 and secondary blood type match with the donor</u>
<u>5</u>	<u>OPO's DSA</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>6</u>	<u>OPO's DSA</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>7</u>	<u>OPO's DSA or Zone A</u>	<u>Pediatric status 1B and primary blood type match with the donor</u>
<u>8</u>	<u>OPO's DSA or Zone A</u>	<u>Pediatric status 1B and secondary blood type match with the donor</u>
<u>9</u>	<u>Zone A</u>	<u>Adult status 1 and primary blood type match with the donor</u>
<u>10</u>	<u>Zone A</u>	<u>Adult status 1 and secondary blood type match with the donor</u>
<u>11</u>	<u>Zone A</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>12</u>	<u>Zone A</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>13</u>	<u>OPO's DSA</u>	<u>Adult status 3 and primary blood type match with the donor</u>
<u>14</u>	<u>OPO's DSA</u>	<u>Adult status 3 and secondary blood type match with the donor</u>
<u>15</u>	<u>OPO's DSA</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>16</u>	<u>OPO's DSA</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>17</u>	<u>OPO's DSA</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>18</u>	<u>OPO's DSA</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>19</u>	<u>Zone A</u>	<u>Adult status 3 and primary blood type match with the donor</u>
<u>20</u>	<u>Zone A</u>	<u>Adult status 3 and secondary blood type match with the donor</u>
<u>21</u>	<u>Zone A</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>22</u>	<u>Zone A</u>	<u>Adult status 4 and secondary blood type match with the donor</u>

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>23</u>	<u>Zone A</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>24</u>	<u>Zone A</u>	<u>Adult Status 5 and secondary blood type match with the donor</u>
<u>25</u>	<u>OPO's DSA</u>	<u>Pediatric status 2 and primary blood type match with the donor</u>
<u>26</u>	<u>OPO's DSA</u>	<u>Pediatric status 2 and secondary blood type match with the donor</u>
<u>27</u>	<u>OPO's DSA</u>	<u>Adult status 6 and primary blood type match with the donor</u>
<u>28</u>	<u>OPO's DSA</u>	<u>Adult status 6 and secondary blood type match with the donor</u>
<u>29</u>	<u>Zone B</u>	<u>Pediatric status 1A and primary blood type match with the donor</u>
<u>30</u>	<u>Zone B</u>	<u>Pediatric status 1A and secondary blood type match with the donor</u>
<u>31</u>	<u>Zone B</u>	<u>Adult status 1 and primary blood type match with the donor</u>
<u>32</u>	<u>Zone B</u>	<u>Adult status 1 and secondary blood type match with the donor</u>
<u>33</u>	<u>Zone B</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>34</u>	<u>Zone B</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>35</u>	<u>Zone B</u>	<u>Pediatric status 1B and primary blood type match with the donor</u>
<u>36</u>	<u>Zone B</u>	<u>Pediatric status 1B and secondary blood type match with the donor</u>
<u>37</u>	<u>Zone B</u>	<u>Adult status 3 and primary blood type match with the donor</u>
<u>38</u>	<u>Zone B</u>	<u>Adult status 3 and secondary blood type match with the donor</u>
<u>39</u>	<u>OPO's DSA</u>	<u>Pediatric status 2 and primary blood type match with the donor</u>
<u>40</u>	<u>OPO's DSA</u>	<u>Pediatric status 2 and secondary blood type match with the donor</u>
<u>41</u>	<u>OPO's DSA</u>	<u>Adult status 6 and primary blood type match with the donor</u>
<u>42</u>	<u>OPO's DSA</u>	<u>Adult status 6 and secondary blood type match with the donor</u>
<u>43</u>	<u>Zone C</u>	<u>Pediatric status 1A and primary blood type match with the donor</u>
<u>44</u>	<u>Zone C</u>	<u>Pediatric status 1A and secondary blood type match with the donor</u>

<u>Classification</u>	<u>Candidates that are within the:</u>	<u>And are:</u>
<u>45</u>	<u>Zone C</u>	<u>Adult status 1 and primary blood type match with the donor</u>
<u>46</u>	<u>Zone C</u>	<u>Adult status 1 and secondary blood type match with the donor</u>
<u>47</u>	<u>Zone C</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>48</u>	<u>Zone C</u>	<u>Adult status 2 and secondary blood type match with the donor</u>
<u>49</u>	<u>Zone C</u>	<u>Pediatric status 1B and primary blood type match with the donor</u>
<u>50</u>	<u>Zone C</u>	<u>Pediatric status 1B and secondary blood type match with the donor</u>
<u>51</u>	<u>Zone C</u>	<u>Adult status 3 and primary blood type match with the donor</u>
<u>52</u>	<u>Zone C</u>	<u>Adult status 3 and secondary blood type match with the donor</u>
<u>53</u>	<u>Zone C</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>54</u>	<u>Zone C</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>55</u>	<u>Zone C</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>56</u>	<u>Zone C</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>57</u>	<u>Zone C</u>	<u>Pediatric status 2 and primary blood type match with the donor</u>
<u>58</u>	<u>Zone C</u>	<u>Pediatric status 2 and secondary blood type match with the donor</u>
<u>59</u>	<u>Zone C</u>	<u>Adult status 6 and primary blood type match with the donor</u>
<u>60</u>	<u>Zone C</u>	<u>Adult status 6 and secondary blood type match with the donor</u>
<u>61</u>	<u>Zone D</u>	<u>Pediatric status 1A and primary blood type match with the donor</u>
<u>62</u>	<u>Zone D</u>	<u>Pediatric status 1A and secondary blood type match with the donor</u>
<u>63</u>	<u>Zone D</u>	<u>Adult status 1 and primary blood type match with the donor</u>
<u>64</u>	<u>Zone D</u>	<u>Adult status 1 and secondary blood type match with the donor</u>
<u>65</u>	<u>Zone D</u>	<u>Adult status 2 and primary blood type match with the donor</u>
<u>66</u>	<u>Zone D</u>	<u>Adult status 2 and secondary blood type match with the donor</u>

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

Classification	Candidates that are within the:	And are:
<u>89</u>	<u>Zone E</u>	<u>Adult status 4 and primary blood type match with the donor</u>
<u>90</u>	<u>Zone E</u>	<u>Adult status 4 and secondary blood type match with the donor</u>
<u>91</u>	<u>Zone E</u>	<u>Adult status 5 and primary blood type match with the donor</u>
<u>92</u>	<u>Zone E</u>	<u>Adult status 5 and secondary blood type match with the donor</u>
<u>93</u>	<u>Zone E</u>	<u>Pediatric status 2 and primary blood type match with the donor</u>
<u>94</u>	<u>Zone E</u>	<u>Pediatric status 2 and secondary blood type match with the donor</u>
<u>95</u>	<u>Zone E</u>	<u>Adult status 6 and primary blood type match with the donor</u>
<u>96</u>	<u>Zone E</u>	<u>Adult status 6 and secondary blood type match with the donor</u>

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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 1A and primary blood type match with the donor
4	OPO's DSA	Adult status 1A and secondary blood type match with the donor
5	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor
6	OPO's DSA or Zone A	Pediatric Status 1B and secondary blood type match with the donor
7	OPO's DSA	Adult Status 1B and primary blood type match with the donor
8	OPO's DSA	Adult Status 1B and secondary blood type match with the donor
9	Zone A	Adult Status 1A and primary blood type match with the donor
10	Zone A	Adult Status 1A and secondary blood type match with the donor
11	Zone A	Adult Status 1B and primary blood type match with the donor
12	Zone A	Adult Status 1B and secondary blood type match with the donor
13	OPO's DSA	Pediatric status 2 and primary blood type match with the donor

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

Classification	Candidates that are within the:	And are:
36	Zone C	Adult status 1A and secondary blood type match with the donor
37	Zone C	Pediatric status 1B and primary blood type match with the donor
38	Zone C	Pediatric status 1B and secondary blood type match with the donor
39	Zone C	Adult status 1B and primary blood type match with the donor
40	Zone C	Adult status 1B and secondary blood type match with the donor
41	Zone C	Pediatric status 2 and primary blood type match with the donor
42	Zone C	Pediatric status 2 and secondary blood type match with the donor
43	Zone C	Adult status 2 and primary blood type match with the donor
44	Zone C	Adult status 2 and secondary blood type match with the donor
45	Zone D	Pediatric status 1A and primary blood type match with the donor
46	Zone D	Pediatric status 1A and secondary blood type match with the donor
47	Zone D	Adult status 1A and primary blood type match with the donor
48	Zone D	Adult status 1A and secondary blood type match with the donor
49	Zone D	Pediatric status 1B and primary blood type match with the donor
50	Zone D	Pediatric status 1B and secondary blood type match with the donor
51	Zone D	Adult status 1B and primary blood type match with the donor
52	Zone D	Adult status 1B and secondary blood type match with the donor
53	Zone D	Pediatric status 2 and primary blood type match with the donor
54	Zone D	Pediatric status 2 and secondary blood type match with the donor
55	Zone D	Adult status 2 and primary blood type match with the donor
56	Zone D	Adult status 2 and secondary blood type match with the donor
57	Zone E	Pediatric status 1A and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
58	Zone E	Pediatric status 1A and secondary blood type match with the donor
59	Zone E	Adult status 1A and primary blood type match with the donor
60	Zone E	Adult status 1A and secondary blood type match with the donor
61	Zone E	Pediatric status 1B and primary blood type match with the donor
62	Zone E	Pediatric status 1B and secondary blood type match with the donor
63	Zone E	Adult status 1B and primary blood type match with the donor
64	Zone E	Adult status 1B and secondary blood type match with the donor
65	Zone E	Pediatric status 2 and primary blood type match with the donor
66	Zone E	Pediatric status 2 and secondary blood type match with the donor
67	Zone E	Adult status 2 and primary blood type match with the donor
68	Zone E	Adult status 2 and secondary blood type match with the donor

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6.5.F Allocation of Heart-Lungs

851 When a heart-lung potential transplant recipient (PTR) candidate is offered allocated a heart, the
852 lung from the same deceased donor must be offered allocated to the heart-lung PTR candidate.

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854 When a heart-lung ~~candidate~~ PTR is ~~allocated~~ offered a lung, the heart from the same deceased
855 donor must be offered ~~may only be allocated~~ to the heart-lung PTR according to Table 6-9 below
856 candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart.

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Table 6-9: Allocation of Heart-Lungs If PTR is Offered the Lung

<u>When a heart-lung PTR in this geographic area is offered a lung:</u>	<u>The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all:</u>	<u>Within this geographic area:</u>
<u>OPO's DSA or Zone A</u>	<u>Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs</u>	<u>OPO's DSA or Zone A</u>
<u>Zone B</u>	<u>Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs</u>	<u>Zone B</u>

<u>When a heart-lung PTR in this geographic area is offered a lung:</u>	<u>The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all:</u>	<u>Within this geographic area:</u>
<u>Zone C</u>	<u>Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs</u>	<u>Zone C</u>
<u>Zone D</u>	<u>Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs</u>	<u>Zone D</u>
<u>Zone E</u>	<u>Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs</u>	<u>Zone E</u>

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The blood type matching requirements described in *Policy 6.5.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* applies to heart-lung candidates when the candidates appear on the lung match run.

OPTN Bylaws

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Appendix K

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K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal

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When a member transplant hospital experiences long-term inactivity, withdraws its designated transplant program status, or its designated transplant program status is terminated, it must:

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1. Immediately suspend organ transplantation for the transplant program.
2. Assist potential candidates and candidates in transferring to other designated transplant programs.
3. Provide a list to the OPTN Contractor of all of the transplant program's candidates on the waiting list at the time of long-term inactivity, withdrawal, or termination and update it throughout this process. The program should indicate on the list of each candidate if:

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- A candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision before they are removed from the waiting list.

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- A candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic status updates will be required that documents each candidate's transfer progress until the candidate is evaluated and accepted on the waiting list by another transplant program or removed from the waiting list.

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- a. Expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN member transplant hospital.
- b. Initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within 7 days of long-term inactivity, withdrawal, or termination. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time, or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and

893 submit to the OPTN contractor all efforts to transfer its hospitalized candidates, if it is unable
894 to meet these time periods.

895 c. Provide a priority list of the most urgent candidates listed at the transplant program with an
896 individualized plan of transfer, potential alternative transplant programs, and a timeline for
897 transferring these candidates according to the following priorities:
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- 899 ■ For liver candidates, all Status 1A and 1B candidates must be transferred within 7 days of
900 long-term inactivity, withdrawal, or termination, followed by all active candidates in
901 descending MELD/PELD score order, with all candidates whose MELD/PELD score
902 exceeds 25 to be transferred within 30 days, followed by all inactive candidates.
- 903 ■ For lung candidates, active candidates should be transferred according to descending
904 Lung Allocation Scores with highest scores first, followed by inactive candidates.
- 905 ■ For kidney candidates, those whose PRA (measured or calculated) is over 80 percent
906 should be transferred first, followed by all other active candidates in order of waiting time,
907 then transfer of all inactive candidates last.
- 908 ■ For heart candidates, all pediatric Sstatus 1A and 1B and adult status 1, 2, 3 and 4 must
909 be transferred within 7 days of long-term inactivity, withdrawal, or termination.
- 910 ■ For multi-visceral organ transplant candidates, transfer must be completed within 30 days
911 of long-term inactivity, withdrawal, or termination.
- 912 ■ All active candidates should be transferred within 60 days of long-term inactivity,
913 withdrawal, or termination without considering these guidelines.
- 914 ■ The program must document and submit to the OPTN Contractor all efforts made for
915 transfer of its candidates if it is unable to meet these deadlines.
- 916 ■ Document all efforts to transfer candidates to an alternative designated transplant
917 program including all contacts made to facilitate the transfer of candidates.
- 918 ■ Remove every transplant candidate from the transplant program's waiting list within 12
919 months of the program's long-term inactivity, withdrawal, or termination date.

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921 A member that experiences long-term inactivity, withdrawal, or termination of a designated
922 transplant program may still have the ability to temporarily provide care to transplant candidates,
923 and provide follow-up care as necessary to transplant recipients and living donors. Should the
924 transplant program continue to provide follow-up care to transplant recipients and living donors,
925 the program must continue to submit OPTN follow up forms through UNetSM. Alternatively,
926 transplant recipients may transfer care to another hospital.

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928 **Appendix M: Definitions**

929 **Regional Review Boards (RRBs)**

930 Peer review panels established in each of the 11 regions to review all urgent status listings for ~~liver and~~
931 ~~heart candidates. The RRB reviews justification forms submitted by each center~~ transplant hospital
932 documenting the severity of the candidate's illness and justifies the status at which the candidate is listed.
933 Liver RRBs review listings for all liver candidates in Status 1, special case exceptions for MELD/PELD
934 liver candidates, and hepatocellular carcinoma (HCC) candidates. Thoracic Heart RRBs review listings
935 exception requests for heart candidates in pediatric Sstatus 1A and 1B heart candidates and adult status
936 1, 2, 3, and 4 and special case heart candidates in pediatric 1B. These boards also consider appeals of
937 cases initially refused for a particular medical urgency status.

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