

*Briefing to the OPTN Board of Directors on*

# **Amend Status Extension Requirements in Adult Heart Allocation Policy**

*OPTN Heart Transplantation Committee*

*Prepared by: Eric Messick*

*UNOS Policy and Community Relations Department*

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# Amend Status Extension Requirements in Adult Heart Allocation Policy

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

## Executive Summary

In late 2018, the Organ Procurement and Transplantation Network (OPTN) implemented substantial changes to the adult heart allocation system.<sup>1</sup> The modifications were intended to better stratify the most medically urgent heart transplant candidates. The changes included expanding the number of adult heart statuses from three to six to give greater priority to heart conditions associated with worse waitlist mortality. To assist transplant programs in determining the appropriate status assignment, more detailed qualifying criteria were added to indicate the circumstances by which a candidate can be initially assigned to a status, and the circumstances by which the candidate would be eligible for an extension of the status assignment.

The prescriptiveness of the qualifying criteria varies within statuses and across statuses. Under the 2018 changes, some policies now require submission of detailed clinical information demonstrating that a candidate's condition continues warranting assignment to that status beyond the initial time period. Conversely, other policies only require submission of another adult heart justification form that includes minimal new information about the candidate.

The OPTN Heart Transplantation Committee (hereafter, the Committee) proposal improves the consistency of adult heart allocation policy and the criteria and circumstances by which a candidate

<sup>1</sup> OPTN Thoracic Organ Transplantation Committee, *Proposal to Modify the Adult Heart Allocation System*, [https://optn.transplant.hrsa.gov/media/1921/thoracic\\_adult\\_heart\\_allocation\\_modification\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1921/thoracic_adult_heart_allocation_modification_20160815.pdf) (accessed June 23, 2021).

qualifies for a status extension. Of note, the updates make clear that a candidate needs to continue meeting the initial qualifying criteria to be eligible for a status extension, including continued hospital admission when appropriate.

During their work on status extension criteria, the Committee identified other opportunities to strengthen adult heart policy. These include replacing the general requirements governing pump thrombosis as a qualifying criteria for status 3 with more specific requirements based on the experience gained since the changes were implemented in October 2018. The Committee also proposes allowing candidates who initially qualified for status 1 under the Mechanical Circulatory Support Device with Life Threatening Ventricular Arrhythmia criterion but whose condition stabilized as a result of the support to qualify for status 3. Currently, the status 1 candidates who are stabilized would qualify for status 4 or status 6.

## Background

This project continues the Committee's previous efforts to address areas of improvement in heart allocation policy. Since implementation of the adult heart allocation policy modifications in October 2018, transplant programs have sought clarification of the requirements associated with extending a candidate's status assignment. For example, some of the modifications resulting in a candidate's transplant program needing to document that the candidate continues meeting medical criteria in order to extend, while others only require submission of another adult heart status justification form without any updated information. Such differences have led to questions about whether new information documenting a candidate's medical condition is required if policy does not explicitly state that it does. Other questions have focused on whether hospitalization is required for an extension if it was required for initial status assignment.

Additionally, Heart Committee members were concerned that some candidates are being assigned to statuses for longer periods of time than necessary, or for which they no longer qualify. To help evaluate these concerns, the Committee<sup>2</sup> reviewed an analysis of the use of extensions and the duration of the extensions. Based on the findings, members noted that extensions for certain statuses and criteria were being used more frequently than was to be expected.

## Adult Heart Status Extension Requirements

Specific requirements listed with extension language are presumed to be all the requirements necessary to meet eligibility. Phrased differently, a candidate does not have to meet requirements that are not explicitly specified as part of the extension language.<sup>3</sup> The consensus of the Committee was that policy should be amended to clarify that certain requirements would apply universally when seeking an extension of a candidate's status assignment. The interpretation that a transplant program could extend a candidate's time assigned to a particular status by simply submitting another heart status justification form concerned members of the Committee.<sup>4</sup>

As discussed, to extend a candidate's status 1 assignment under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device*, a transplant program is only required to submit the Heart Justification from within UNet<sup>SM</sup> for the candidate to be assigned at status 1 for another seven days. Under the circumstances, a transplant program does not need to demonstrate that the candidate re-meets the initial qualifying criteria to extend. Nor does a transplant program have to provide objective evidence demonstrating that the candidate continues to meet the established criteria.

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<sup>2</sup> The OPTN Heart Transplantation Committee was officially created on July 1, 2020, and work before that time was performed by the OPTN Thoracic Organ Transplantation Committee. "Committee" in this proposal means either the Thoracic Committee of the Heart Committee depending on that point in time. OPTN, Notice of OPTN Policy, Bylaw, and Guidelines Changes, *Creation of OPTN Heart and Lung Committees*. <https://optn.transplant.hrsa.gov/media/3721/thoracic-split-policy-notice-march-2020.pdf> (Accessed June 23, 2021).

<sup>3</sup> OPTN Thoracic Committee, Meeting minutes from April 17, 2019, [https://optn.transplant.hrsa.gov/media/2960/20190417\\_thoracic\\_minutes.pdf](https://optn.transplant.hrsa.gov/media/2960/20190417_thoracic_minutes.pdf) (access June 22, 2021).

<sup>4</sup> OPTN Thoracic Heart Subcommittee, Meeting minutes from June 27, 2019, [https://optn.transplant.hrsa.gov/media/3307/20190627\\_thoracic\\_heart-subcommittee\\_meeting-minutes.pdf](https://optn.transplant.hrsa.gov/media/3307/20190627_thoracic_heart-subcommittee_meeting-minutes.pdf) (accessed June 22, 2021).

**Table 1** identifies the current policy requirements a status 1 candidate must meet to have his or her assignment extended. *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* includes very specific language detailing the “objective evidence” a transplant program must provide to the regional review board (RRB) when requesting an extension. The evidence includes information that the candidate demonstrated a contraindication to support from a durable device and that the program failed to wean the candidate from VA ECMO as evidenced by hemodynamic data associated with a candidate still requiring support from the device.

**Table 1: Current Policy Requirements Associated With Extending an Adult Heart Candidate’s Status 1 Assignment**

Policy	Requirements to Extend a Candidate’s Stay at Status 1
<p><i>6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)</i></p>	<p>Every 7 days, the transplant program may apply to the regional review board (RRB) to extend the candidate at this status if the candidate remains supported by VA ECMO.</p> <p>The transplant program must provide to the RRB objective evidence of both of the follow:</p> <ol style="list-style-type: none"> <li>1. The candidate demonstrated a contraindication to being supported by a durable device</li> <li>2. Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from VA EMCO as evidenced by at least one of the following: <ul style="list-style-type: none"> <li>• Mean arterial pressure (MAP) less than 60 mmHg</li> <li>• Cardiac index less than 2.0 L/min/m<sup>2</sup></li> <li>• Pulmonary capillary wedge pressure greater than 15 mm Hg</li> <li>• SvO<sub>2</sub> less than 50 percent measured by central venous catheter</li> </ul> </li> </ol> <p>The RRB will retrospectively review extension requests.</p>
<p><i>6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device</i></p>	<p>This status can be extended by the transplant program every 7 days by submission of another <i>Heart Status 1 Justification Form</i>.</p>
<p><i>6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Arrhythmia</i></p>	<p>This status can be extended by the transplant program every 14 days by submission of another <i>Heart Status 1 Justification Form</i> if the candidate remains hospitalized on continuous intravenous antiarrhythmic therapy.</p>

However, continuing a candidate’s status 1 assignment based on either of the other criteria is less burdensome. Extending a candidate assigned to status 1 under the requirements found in *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* only requires submission of another *Heart Status 1 Justification Form*. However, for a status 1 candidate under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Arrhythmia*, the candidate must still be hospitalized in addition to submitting a *Heart Status 1 Justification Form*.

## Use of Adult Heart Status Extensions

An analysis of status extension usage suggested to the Committee that transplant programs are submitting a large number of extension forms on behalf of candidates who are then spending a substantial amount of time at those statuses. **Table 2** shows the number of candidates ever-waiting and the number ever-waiting as part of a status extension between October 18, 2018 and August 31, 2021 by the statuses and criteria of interest to the Committee. (The new adult heart allocation modifications went into effect on October 18, 2018.) The Committee members noted that of the 938 candidates ever-waiting at one of the identified criteria, 489, or more than half, had their assignment extended at least once.<sup>5</sup> Committee members also expressed concerns about the high number of extensions per candidate for some of the identified criterion.

**Table 2: Extension Information by Medical Urgency Status for Candidates Ever-Waiting from 10/18/2019 to 08/31/2021 and Criteria**

Status	Criteria	# of Candidates Ever-Waiting	# of Candidates Ever-Waiting Under Extension	Extension Forms Submitted	Extensions Per Candidate
1	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	107	25	51	0.48
2	Ventricular Tachycardia (VT) or Ventricular Fibrillation (VT)	120	23	37	0.31
3	MCSD with Pump Thrombosis	120	98	1,258	10.48
3	MCSD with Right Heart Failure	47	33	254	5.40
3	MCSD with Device Infection – Erythema	93	41	311	3.34
3	MCSD with Device Infection – Debridement	166	120	951	5.73
3	MCSD with Device Infection – Bacteremia	278	147	617	2.22
3	MCSD with Device Infection – Recurrent Bacteremia	35	5	12	0.34
3	MCSD with Device Infection –Positive Culture	33	11	30	0.91
<b>Total</b>		<b>938</b>	<b>489</b>	<b>3,521</b>	<b>3.75</b>

Note: Based on OPTN data as of October 1, 2021. Data subject to change based on future data submissions or corrections. Columns may sum to more than the total number of candidates because candidates could wait at more than one status/criteria.

Source: OPTN Heart Transplantation Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest – Updated*, October 6, 2021, pp. 3-4.

The Committee also looked more closely at the 489 candidates who had ever waited and used at least one extension. **Table 3** identifies the number of status extensions used and the number of days candidates spent assigned to the status as the result of an extension. (Days spent are generally a function of the permissible number of days for an extension established in policy and the number of extensions used.)

<sup>5</sup> OPTN Heart Transplantation Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest – Updated*, October 6, 2021, p. 3.

**Table 3: Number of Extensions and Days Spent Under an Extension by Medical Urgency Status for Candidates Ever-Waiting from 10/18/2019 to 08/31/2021 and Criteria**

Status	Criteria	Average # Used	Median # Used	Days in Policy	Average # of Days Used	Median # of Days Used
1	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	1	7	21	8
2	Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)	3	1	14	16	12
3	MCS D with Pump Thrombosis	13	8	14	183	120
3	MCS D with Right Heart Failure	8	4	14	108	60
3	MCS D with Device Infection – Erythema	8	6	14	108	78
3	MCS D with Device Infection – Debridement	8	5	14	111	60
3	MCS D with Device Infection – Bacteremia	4	3	42	159	84
3	MCS D with Device Infection – Recurrent Bacteremia	2	2	90	158	100
3	MCS D with Device Infection – Positive Culture	2	2	90	186	125

Note: Based on OPTN data as of October 1, 2021. Data subject to change based on future data submissions or corrections. Source: OPTN Heart Transplantation Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest - Updated*, October 6, 2021, p. 6.

The Committee considered this information to help determine whether the number of days candidates were spending at a particular status and criterion by way of an extension appear appropriate based on the requirements. For example, *Policy 6.1.B.vi: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)* permits assignment for up to 14 days under an extension. As shown in the table, the median number of extensions used was one, and the median days spent was 12. This suggests that candidates assigned to this criterion by extension used fewer days (12) than policy allows (14).

However, the members suggested that the use of extensions for some status criterion did not necessarily appear aligned with policy intent or clinical practice. The average of 13 extensions submitted on behalf of candidates assigned to MCS D with pump thrombosis was concerning to the Committee members. Many members were surprised by the high number of extensions and long duration of the assignments because of the increased patient risk associated with pump thrombosis. According to the Committee, completely eliminating a pump thrombosis is very challenging. Patients with pump thrombosis may be at risk for stroke or hemolysis. Transplant programs are often cautious with such patients and may be inclined to replace the patient’s pump within a relatively short timeframe.

In addition to MCS D with pump thrombosis, the Committee identified the use of status extensions for candidates assigned to MCS D with right heart failure, device infection with erythema and device infection with debridement as areas for attention. (It is important to note that candidates in more medically urgent statuses have much shorter median time to transplant, resulting in less need to submit as many extension forms.)

As a result of the potential overuse of status extensions within certain status criteria, as well as member questions seeking clarification about the eligibility led the Committee to determine that policy modifications were necessary. The Committee members agreed that clarifying existing status requirements and making the requirements consistent across statuses would resolve many of the

identified issues. Their proposed changes included whether to add policy requirements for a candidate to meet in order to be eligible for an extension of their status. The Committee also considered how increasing or decreasing the number of days a status assignment can be extended might improve program's understanding of policy. Based on the results of the data analysis, the Committee also believed that revision of the pump thrombosis policy would have substantial benefits to the patients and the transplant programs.

## Purpose

This proposal offers policy changes to address issues associated with extension requirements in certain policies and qualifying criteria. Among the issues are concerns regarding the inconsistency in extension requirements across adult heart allocation statuses and criteria. Additionally, the variability in the length of time provided under extension requirements across statuses and criteria also raised questions about how consistently candidates with similar medical urgencies are treated. The Committee also concluded that the policy addressing candidates with MCSD with Pump Thrombosis could be improved through changes to reflect current clinical practice better.

The Committee proposes the changes to ensure that similarly situated heart candidates have equitable opportunities to receive an organ offer. The Committee also views the changes in tandem with their efforts approved by the OPTN Board of Directors in 2020 to address the use of status 2 exceptions to better align candidates based in their medical urgencies.<sup>6</sup>

## Proposal for Board Consideration

The Committee proposes clarifying that certain policies require demonstrating a candidate continues meeting certain criteria in order to extend the assignment at the status. The Committee also proposes changing some of the initial qualifying timeframes and extension timeframes to better align them within statuses and/or medical urgencies as appropriate. The Committee proposes revising policy addressing MCSDs with pump thrombosis to reflect better the medical conditions patients experience and the associated treatments. Finally, the proposal provides candidates assigned to status 1 by MCSD with life threatening ventricular arrhythmia who are subsequently stabilized by the support access to assignment as status 3 candidates.

The Committee members considered the feedback received during public comment, and decided to leave the proposal largely unchanged. However, the Committee decided to re-phrase the wording associated with the extension criteria as it appeared in the public comment document. The revised wording clarifies the intent of the extension criteria and improving overall consistency within adult heart allocation policy. The change is described in more detail later in this section.

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<sup>6</sup> Briefing to the OPTN Board of Directors on Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy, OPTN Heart Transplantation Committee, December 2020, [https://optn.transplant.hrsa.gov/media/4224/briefing-paper\\_dec-2020\\_guidance-and-policy-clarifications-addressing-adult-heart-allocation-policy.pdf](https://optn.transplant.hrsa.gov/media/4224/briefing-paper_dec-2020_guidance-and-policy-clarifications-addressing-adult-heart-allocation-policy.pdf) (accessed October 29, 2021).

## Clarifying Extension Requirements to Improve Adult Heart Allocation Policy Consistency

The Committee proposes amending adult heart allocation policy to better ensure that transplant programs demonstrate that a candidate continues to meet eligibility criteria in order to remain in the assigned status beyond the initial qualifying timeframe. They propose several ways to accomplish this goal. Requiring that a candidate meet appropriate criteria to extend his or her stay at a status promotes equity in access to transplant because it better aligns the candidate's current medical urgency with the appropriate heart status. The proposed changes also seek to make policy more consistent by introducing similarly detailed criteria to extend a candidate's time at a status, where current policies are more open-ended.

To help achieve their goal of ensuring the use of status extensions is reserved for patients continuing to experience the qualifying criteria, the Committee amended several policies by adding the phrase "...if the candidate continues to meet the [initial] criteria..." The clarification underscore that status extensions were intended to address an on-going problem. It is also intended to curtail situations where a candidate has not experienced the problem recently by highlighting that the conditions should have occurred during the initial qualifying timeframe.

The Committee also proposed including a hospitalization reference to the three status 1 criteria to ensure consistency. The members agreed that this status needs to be reserved for the most medically urgent candidates, and that such candidates should be admitted to the hospital. While a patient assigned to any of the three status 1 criteria is likely to be hospitalized when receiving treatment, current policy does not explicitly state it.

The Committee proposes the following changes: In order to extend a candidate's status 1 assignment under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCS) with Life Threatening Ventricular Arrhythmia*, the candidate must remain "hospitalized on continuous intravenous antiarrhythmic therapy." The Committee also proposes adding language to *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* and *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* clearly indicating that a candidate must remain hospitalized in order to qualify for a status extension.

To promote consistency, the Committee is proposing additional changes to *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCS) with Life Threatening Ventricular Arrhythmia*. A candidate who no longer qualifies for status under the criterion would likely need to be assigned to status 6, unless the candidate meets another status by standard criteria. The Committee agreed that status 6 is not necessarily an appropriate assignment for such candidates based on their medical condition. It was noted that such candidates are stabilized. However, they still require a level of care greater than the assistance available through the status 4 criteria. Drawing upon their own clinical experiences, the Committee members agreed that candidates in these circumstances are more aligned with the Ventricular Assist Device (VAD) complications addressed in status 3. Furthermore, not having a specific status for such candidates to transition to could be contributing to the number of exception requests submitted for status 1, according to the Committee.

The Committee proposes improving the situation by adding a new criterion within status 3 that would allow for transplant programs to transition a candidate who no longer is eligible for status 1 assignment

under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia*. The Committee modeled the proposed policy on existing status 3 language for candidates transitioning from status 1 under the *Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)*. Creating a status 3 “stepdown” or transition policy for such candidates provides transplant programs with an alternative that more closely aligns with the candidate’s medical condition than status 6.

Currently, a transplant program can extend a candidate’s assignment to status 3 under *Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection* by submitting another *Heart Status 3 Justification Form*. The program is not required to provide additional information demonstrating that the candidate continues meeting any of the criteria associated with the status. After considering the circumstances, the Committee determined that it would be appropriate to require a candidate to continue meeting the criteria he or she initially qualified under and that the candidate experienced the condition within the timeframe associated with those criteria in policy. The Committee also proposes amending the extension requirement to include the current use of intravenous (IV) antibiotics to treat the candidate’s condition.

In addition to clarifying the policy language defining extension criteria, the Committee proposes changing the number of days a candidate can be assigned to an adult heart status initially and by extension. According to Committee’s two-year monitoring report of adult heart allocation policy implementation, candidates listed at status 3 experienced large variability in median time to transplant depending on the criterion to which they were assigned.<sup>7</sup> This suggests that not all candidates assigned to status 3 are perceived as having the same medical urgency. (It is important to note that some of the status 3 criteria have small sample sizes, and therefore the estimates may be less precise.)

**Table 4** illustrates that MCSD with pump thrombosis, MCSD with right heart failure, and MCSD with pump infection all have longer median days to transplant than the other status 3 criteria. Finally, the number of transplants that occurred when a candidate was at status 3 by extension accounted for approximately 33 percent of all transplants of status 3 candidates. Based on these considerations and the potential for a candidate to remain assigned to the status for extended periods as the result of multiple extensions, the Heart Committee proposes several policy changes.

**Table 4: Median Days to Transplant for Adult Status 3 Candidates  
Between October 18, 2018 and October 17, 2020**

Criteria	Median Days to Transplant
MCSD with Right Heart Failure	162
MCSD with Infection	77
MCSD with Pump Thrombosis	67
MCSD with Aortic Insufficiency	61
LVAD	45
<b>Median for All Status 3 Candidates Waiting Before Transplant</b>	<b>26</b>
Exception	26
Multiple / Single High Dose Inotropes and Hemodynamic Monitoring	17
MCSD with Hemolysis	10

<sup>7</sup> OPTN Heart Transplantation Committee, "Two-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," March 16, 2021, Figure 30: Median Days to Transplant by Criteria within Medical Urgency Status Post-Implementation, p. 60.

Note: The Heart Committee used the 18-month monitoring report to help initially identify which statuses and criterion to address. The median days to transplant for MCSD with mucosal bleeding was not included in the 18-month monitoring report because the sample size was too small.

Source: OPTN Heart Transplantation Committee, "Two-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," March 16, 2021, Table17: Median Days to Transplant by Medical Urgency Status and Criteria Post-Implementation, p. 61.

The proposed changes to the number of days available as part of an initial or extension assignment are identified in **Table 5**. As previously mentioned, the Committee members agreed that the status 1 criteria should reflect the same number of days for an extension to reflect the medical urgency of the status. The Committee also determined that extending the number of days for MCSD with pump thrombosis and right heart failure were based appropriately on a mixture of medical urgency and the previous use of extensions.

**Table 5: Proposed Changes to Number of Days Assigned at Status**

Status	Policy	Current # of Days Assignment Is Valid for Under Initial Request	Proposed # of Days Assignment Is Valid for Under Initial Request	Current # of Days Assignment Is Valid for Under Extension Request	Proposed # of Days Assignment Is Valid for Under Extension Request
1	6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia	14	7	14	7
3	6.1.C.iv: MCSD with Pump Thrombosis	14	30	14	90
3	6.1.C.v: MCSD with Right Heart Failure	14	14	14	90

## Revising Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCS) with Pump Thrombosis

The Committee proposes clarifying the intent of *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCS) with Pump Thrombosis*. Currently, the policy does not provide as much detail in describing the symptoms and treatments necessary for assigning a patient to this status, as certain other policies do. Additionally, transplant programs submitted, an average of 12 extensions per candidate assigned to the MCS with pump thrombosis criterion, as previously shown in **Table 3**. Furthermore, the policy does not identify a temporal relationship between when a patient experiences the symptoms and when the request for assignment at the status should occur. According to Committee members, the policy could currently be interpreted as allowing a patient who had experienced a very remote event to qualify for this status (e.g. a stroke five years ago associated with ventricular assist device (VAD) issues, but no events since then). The proposed clarification increases the granularity of the standard criteria and establishes a temporal relationship between a candidate experiencing the identified symptoms and receiving treatment in the hospital.

To make the policy more detailed, the revisions focus on the suspected pump thrombosis symptoms that are likely to occur and the therapies used to treat such symptoms. The Committee members used their collective experience in attending such patients to guide their determinations. They agreed that

adding specificity to the symptoms and treatments would make the criterion more consistent with similar status 3 criteria. The changes should assist transplant programs with identifying whether a candidate truly meets the intended requirements. The Committee discussed that in order for a candidate to qualify for status 3 using this criterion, at least one of the criteria describing the symptoms of pump thrombosis had to be met. Additionally, there was consensus that hospitalization is an appropriate requirement for assignment at status 3 if a candidate is experiencing pump thrombosis, but seeking transplantation rather than having the pump replaced.

The Committee debated what would be the appropriate number of days to provide under an extension. Currently, the status is valid for up to 14 days for both the initial assignment and the extension. The Committee acknowledged that it is time consuming to determine whether a candidate is best served by a transplant rather than a pump replacement or other type of treatment. As a result, they did not want to propose a timeframe that would unnecessarily restrict a transplant program's ability to make a judicious decision. The Committee also considered the large volume of extensions used for these patients. The Committee was reminded that an objective of this status extension project was to ensure that the criteria are fairer and not make it more difficult for candidates to be listed at status 3. Based on these factors, the Committee proposes increasing the initial qualifying period from 14 to 30 days, and the extension timeframe from 14 to 90 days. During their earlier deliberations, the Committee had compared MCS D with pump thrombosis with *Policy 6.1.C.vii: MCS D with Mucosal Bleeding*, where the extension timeframe is 90 days.<sup>8</sup> The members agreed that because the two policies are similar, having their timeframes be consistent was appropriate. The Committee also referenced the frequent use of status extensions and the extended median days to transplant for these candidates as part of their reasoning to increase the extension timeframe.

## Overall Sentiment from Public Comment

The proposal was available for public comment from August 3 through September 30, 2021. The Committee requested feedback about the proposed changes to *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCS D) with Pump Thrombosis*. The Committee asked the community if the proposed policy clearly described the clinical conditions and treatments so as to be easily understood by transplant program staff and consistently interpreted across transplant programs. In addition, the Committee requested feedback as to whether the policy should be further amended to include a temporal relationship aligning when a patient experienced the clinical conditions and when the treatments are provided.

Community input was also sought about whether all extension criteria should require the submission of objective evidence of a candidate's medical condition demonstrating a continued need for the established therapies. The Committee also asked the public to weigh in on whether certain populations of adult heart candidates are treated inconsistently in terms of the extension requirements.

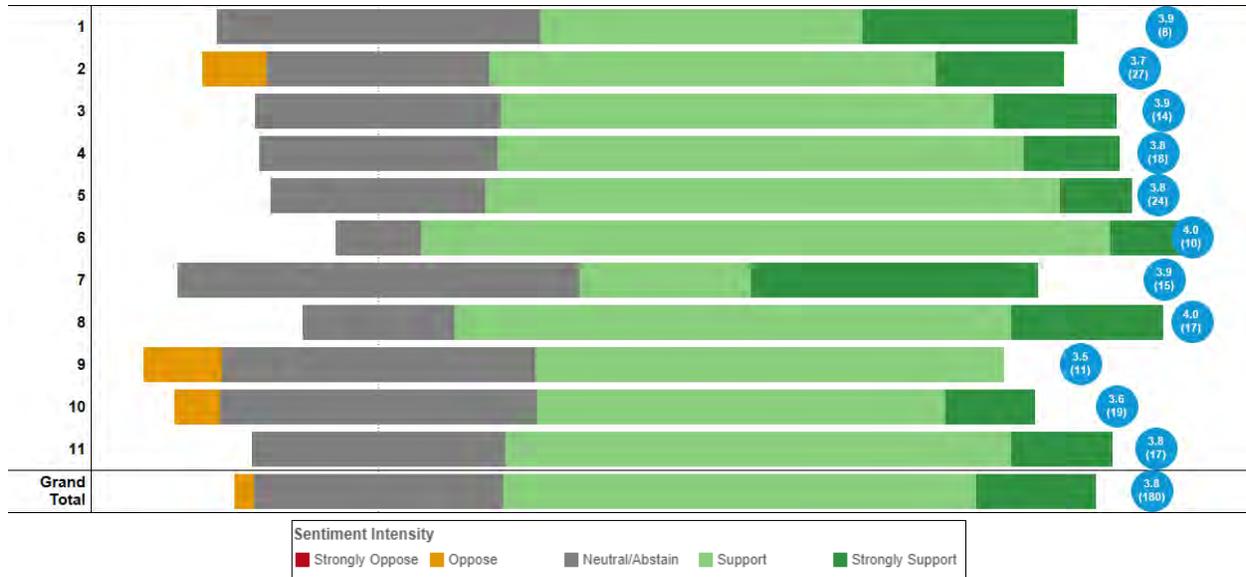
The primary theme from public comment consisted of overall support for clarifying the status extension criteria and making the policy more consistent overall. Some concerns were raised about the changes to the number of days available at an assigned status. Each theme is described in more detail.

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<sup>8</sup> OPTN Heart Transplantation Committee, Meeting Summary, January 20, 2021.

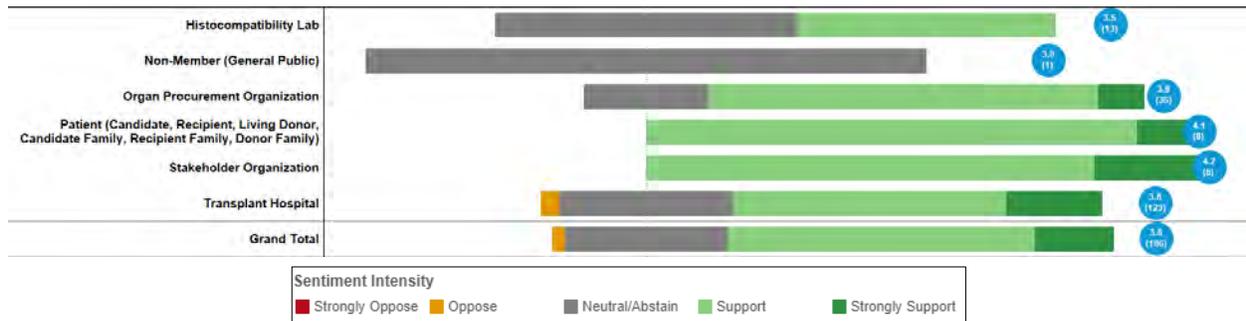
**Figure 1** categorizes the sentiment information submitted as part of the 11 regional meetings.<sup>9</sup> As shown by the Grand Total bar, sentiment was largely supportive of the proposal within each region.

**Figure 1: Sentiment Support for the Proposal, by Region**



The proposal was also broadly supported across members types as demonstrated by the Grand Total bar (**Figure 2**).<sup>10</sup> During the regional meetings, a total of 129 members indicated support for the proposal while only four members indicated opposition to it.

**Figure 2: Sentiment Support for the Proposal, by Member Type**



Four professional organizations submitted written comments regarding the proposal. The American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the Association of

<sup>9</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

<sup>10</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Organ Procurement Organizations (AOPO), and the Organization for Donation and Transplantation Professionals (NATCO) all indicated support for the proposal. While supportive of the proposal, NATCO's response suggested that increasing the timeframe to up to 90 days for extending a candidate's status 3 assignment using the MCSD with Pump Thrombosis criteria might be too long. The Committee took such comments very seriously and for the most part agreed with the concerns that a pump replacement might be more appropriate after the proposed amount of time. Despite the concerns expressed during public comment that 90 days may be too long, the Committee chose to keep the timeframe. As discussed in the previous section, the Committee considered the number of days for the extension in light of the median days to transplant for current candidates, as well as the extension timeframe established in *Policy 6.1.C.vii: MCSD with Mucosal Bleeding*, a policy they considered to be addressing similar concerns.

The Committee also received feedback that shortening the initial and extension timeframes to seven days for *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Devices* might increase transplant programs' workload related to completing additional justification forms. In particular, some commenters worried that establishing a seven day re-justification timeframe would require substantially more work on the part of the transplant programs when compared to maintaining the 14-day period. The Committee members were in agreement that the status 1 criteria should utilize consistent timeframes that reflect the high medical urgency of the patients assigned to it.

## Compliance Analysis

### NOTA and OPTN Final Rule

The Heart Committee developed the policy proposal under the authority of the OPTN Final Rule, which states, "The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation of cadaveric organs... ." <sup>11</sup> This proposal seeks to clarify and make more consistent adult heart allocation policies for extending a candidate's assignment to a certain status and criteria.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with § 121.8." <sup>12</sup> This proposal is consistent with § 121.8 because it:

- **Is based on sound medical judgment.** <sup>13</sup> This proposal recommends several evidence-based policy changes. The recommendations rely on the medical judgment of the Committee members who based their decisions on OPTN data analyses and their collective clinical experience in treating heart transplant candidates. <sup>14</sup>
- **Is seeking to achieve the best use of donated organs.** <sup>15</sup> One of the best uses of a donated organ is for it to be transplanted according to medical urgency. The Committee's proposed changes to the extension language in adult heart policy are intended to ensure that a candidate's correct

<sup>11</sup> 42 C.F.R. § 121.4(a)(1)

<sup>12</sup> *Id.*

<sup>13</sup> 42 C.F.R. § 121.8(a)(1)

<sup>14</sup> OPTN Heart Transplantation Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest – Updated*, October 6, 2021, p. 8.

<sup>15</sup> 42 C.F.R. § 121.8(a)(2)

medical urgency designation, as indicated by their urgency status, is accurately maintained and used for prioritization.

- **Is specific for each organ**<sup>16</sup>, in this case heart.
- **Is designed to promote access to transplantation.**<sup>17</sup> The proposed changes seek to ensure that similarly situated candidates have equitable opportunities to receive an organ offer. The proposal does this by clarifying extension criteria to make it more consistent for candidates across all statuses, as well as within the statuses.

The changes recommended by the Committee also preserve the ability of a transplant program to decline an offer or not to use the organ for a potential recipient.<sup>18</sup>

This public comment proposal addresses certain aspects of the Final Rule listed above, and the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs.<sup>19</sup>
- Shall be designed to avoid futile transplants.<sup>20</sup>
- Shall be designed to promote the efficient management of organ placement.<sup>21</sup>
- Shall not be based on the candidate's place of residence or place of listing.<sup>22</sup>

The Final Rule requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.<sup>23</sup> During their discussions, the Committee considered whether any particular patient groups would be treated less favorably under the proposed policy changes. Under the proposed policy changes, some adult heart candidates will no longer qualify for extensions because they will no longer meet the initial qualifying criteria. However, the Committee is not recommending a transition procedure because their proposed changes are targeted specifically at making the extension requirements more consistent, and thus fairer, for all adult heart patients. It is proposed that when the policy changes are implemented, a candidate assigned to a status by extension will be allowed to complete the timeframe associated with the extension. However, at the end of the extension timeframe, a candidate's transplant program will no longer be able to extend the candidate's status because the criteria will be different. Instead, the candidate's transplant program would need to submit an initial heart justification form. System programming changes will accommodate this action.

The OPTN proposes collecting additional data on heart candidates that qualify for the new status 3 criteria under the authority of the OPTN Final Rule, which requires the OPTN to: “(i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants; (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients; [and] (iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested...”<sup>24</sup> As a result of the creation of the new

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<sup>16</sup> 42 C.F.R. § 121.8(a)(4)

<sup>17</sup> 42 C.F.R. § 121.8(a)(5)

<sup>18</sup> 42 C.F.R. § 121.8(a)(3)

<sup>19</sup> 42 C.F.R. § 121.8(a)(5)

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> 42 C.F.R. § 121.8(a)(8)

<sup>23</sup> 42 C.F.R. § 121.8(d)(1)

<sup>24</sup> 42 C.F.R. § 121.11(a)(1)(i)-(iii)

“stepdown” status 3 criteria, the OPTN will be collecting new data elements in Waitlist<sup>SM</sup> for those heart candidates.

## OPTN Strategic Plan

*Provide equity in access to transplants:*

This policy proposal supports the OPTN strategic goal of increasing equity in access to transplant. Clarifying how a candidate qualifies for an extension should help ensure that clinical statuses are accurately aligned to transplant candidates’ medical acuity.

## Implementation Considerations

### Member and OPTN Operations

#### *Operations affecting Histocompatibility Laboratories*

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

#### *Operations affecting Organ Procurement Organizations*

This proposal is not anticipated to affect the operations of organ procurement organizations.

#### *Operations affecting Transplant Hospitals*

This proposal will require transplant program staff to become familiar with updated OPTN data collection forms requirements for assigning a candidate to certain adult heart statuses, and potentially extending a candidate’s stay at some statuses. Transplant programs will need to familiarize themselves with changes to the adult heart justification forms. The forms will be updated to reflect the changes resulting in revised criteria and permissible lengths of stay at statuses.

#### *Operations affecting the OPTN*

The proposed policy changes are likely to result in the need for IT programming changes. For example, adding policy requirements to extend a candidate’s status will require that those requirements also be added, in some way, to the existing heart justification forms. As a result, additional programming will be needed, at least initially.

The Committee is aware that by adding extension criteria, there may be an unintended increase in the number of exceptions submitted by transplant programs. The members indicated that the Regional Review Boards probably have the capacity to address such an increase, at least initially. The OPTN will monitor the number of requests for potential changes in volume.

## Projected Fiscal Impact

This proposal is expected to have a fiscal impact on the OPTN and a minimal impact on transplant hospitals, but it is not anticipated to have any fiscal impact on organ procurement organizations or histocompatibility laboratories.

### *Projected Impact on Histocompatibility Laboratories*

There is no expected impact for histocompatibility laboratories.

### *Projected Impact on Organ Procurement Organizations*

There is no expected impact for OPOs.

### *Projected Impact on Transplant Hospitals*

There is an expected minimal impact for transplant hospitals. The proposed modifications to the status extension requirements will require minimal staff training but will not alter existing processes and workflows or require new data collection.

### *Projected Impact on the OPTN*

The Heart Committee sponsored an effort to clarify and specify the requirements surrounding status exceptions in current policy. This proposal seeks to clarify the specific information required for patients to remain at medically urgent status.

The initial implementation estimate, 20 hours, is believed to still be accurate within PCR. Member Quality estimates 150 implementation hours will be required for their staff training, as well as revisions to monitoring documentation and tools. However, no increase to monitoring efforts will be required. Likewise, Professional Education anticipates 100 implementation hours will be required to create an education offering for release in late 2022. IT is estimating it will need 1556 implementation hours to amend elements in Waitlist. These include editing the Adult Heart Status 3 Justification form, editing the Adult Heart Status 1 Justification form, and the creation of a new extension for Device Infection.

IT also will need 153 ongoing hours to maintain this project and provide support for their update to the data elements. Research estimates a very small number of ongoing hours will be required, reflecting a monitoring report at 6 months and 1 year, as well as the complexity of pulling extension data.

## Post-implementation Monitoring

### Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program.”<sup>25</sup>

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<sup>25</sup> 42 CFR §121.8(a)(7)

This proposal will not change the current routine monitoring of OPTN members. At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in UNet<sup>SM</sup> to justify a candidate's status are consistent with documentation in the candidate's medical record.

## Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”<sup>26</sup> This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available (Appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy. Timeline is subject to change based on the results. Data will be presented in tabular and graphical form as appropriate.

The following metrics stratified by criteria within medical urgency status, and any others subsequently requested by the Committee, will be evaluated:

- The number and percent of waitlist additions
- The number and percent of transplants
- The number of initial and extension forms submitted
- The number of adult heart candidates ever waiting at specific medical urgency criteria
- The number of adult heart candidates ever waiting with at least one extension at the specific medical urgency criteria of interest
- Minimum, maximum, average and median number extensions (consecutive and non-consecutive) submitted for the specific medical urgency criteria of interest
- The average number of days spent at each of the medical urgency criteria of interest for candidates ever waiting at medical urgency criteria of interest

## Conclusion

This proposal represents an effort to address issues with adult heart allocation policy. The proposed changes focus on clarifying the requirements for extending a candidate's assignment at certain statuses and certain criteria. In most cases, this involves adding language stating that a candidate needs to continue meeting the initial qualifying criteria, including remaining hospitalized following the initial assignment and/or still receiving treatment for the initial qualifying condition, such as intravenous antibiotics. In another effort to improve consistency, the proposal changes the number of days a candidate is eligible for assignment at certain status 1 and 3 criteria under both the initial and extension qualifying periods. The Committee members also agreed that a candidate who no longer meets the requirements for assignment under *Policy 6.1.A.iii: MCS D with Life Threatening Ventricular Arrhythmia* should not be required to be reassigned at status 6. The proposal adds a new status 3 criterion to help candidates transition to a more appropriate status based on their medical urgency. Finally, the Committee proposes clarifying *Policy 6.1.C.iv: MCS D with Pump Thrombosis* to better address the medical conditions and treatments the criterion is intended to address.

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<sup>26</sup> 42 CFR §121.8(a)(6)

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

85 After 7 days, if the candidate remains hospitalized and the transplant program does  
 86 not request an extension, then the transplant program may assign the candidate to  
 87 status 3.  
 88

### 89 **6.1.C Adult Heart Status 3 Requirements**

90 To assign a candidate to adult status 3, the candidate's transplant program must submit a *Heart*  
 91 *Status 3 Justification Form* to the OPTN. A candidate is not assigned adult status 3 until this form  
 92 is submitted.  
 93

94 If the candidate is at least 18 years old at the time of registration then the candidate's transplant  
 95 program may assign the candidate adult status 3 if the candidate has at least *one* of the  
 96 following conditions:  
 97

- 98 • Is supported by a dischargeable left ventricular assist device and is exercising 30 days of  
 99 discretionary time, according to *Policy 6.1.C.i* below.
- 100 • Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic  
 101 monitoring, according to *Policy 6.1.C.ii* below.
- 102 • Is supported by a mechanical circulatory support device (MCS) with hemolysis, according  
 103 to *Policy 6.1.C.iii* below.
- 104 • Is supported by an MCS with pump thrombosis, according to *Policy 6.1.C.iv* below.
- 105 • Is supported by an MCS and has right heart failure, according to *Policy 6.1.C.v* below.
- 106 • Is supported by an MCS and has a device infection, according to *Policy 6.1.C.vi* below.
- 107 • Is supported by an MCS and has bleeding, according to *Policy 6.1.C.vii* below.
- 108 • Is supported by an MCS and has aortic insufficiency, according to *Policy 6.1.C.viii* below.
- 109 • Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7  
 110 days, according to *Policy 6.1.C.ix* below.
- 111 • Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular  
 112 assist device (LVAD) after 14 days, according to *Policy 6.1.C.x* below.
- 113 • Is supported by a percutaneous endovascular mechanical circulatory support device after 14  
 114 days, according to *Policy 6.1.C.xi* below.
- 115 • Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to *Policy*  
 116 *6.1.C.xii* below.
- 117 • Is supported by a MCS and has life threatening ventricular arrhythmia after 7 days,  
 118 according to *Policy 6.1.C.xiii* below.  
 119

#### 120 **6.1.C.iv Mechanical Circulatory Support Device (MCS) with Pump** 121 **Thrombosis**

122 A candidate's transplant program may assign a candidate to adult status 3 if the  
 123 candidate is admitted to the transplant hospital that registered the candidate on the  
 124 waiting list, is supported by an MCS, and is experiencing pump thrombosis as  
 125 evidenced by at least one of the following and the transplant program has identified  
 126 a suspected pump thrombosis in either an implanted LVAD or a dischargeable  
 127 paracorporeal device and both of the following criteria are met:  
 128

- 129 • ~~Visually detected thrombus in a paracorporeal ventricular assist device (VAD)~~

- 130 ● ~~Transient ischemic attack, stroke, or peripheral thromboembolic event, with~~  
 131 ~~non-invasive testing to exclude both:~~  
 132 ~~1. Intracardiac thrombus in all candidates~~  
 133 ~~2. Significant carotid artery disease in candidates with a neurological event~~  
 134 ● The candidate has one of the following conditions:  
 135 ○ Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible  
 136 Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as  
 137 observed by symptoms such as, but not limited to unilateral facial  
 138 weakness, vision problems, and/or slurred speech), Cerebrovascular  
 139 Accident (CVA), or peripheral thromboembolic event in the absence of  
 140 intracardiac thrombus or significant carotid artery disease,  
 141 ○ A condition that requires inotropic support and presence of left-sided  
 142 heart failure not explained by structural heart disease such as Aortic  
 143 Insufficiency (AI) [as defined Policy 6.1.C.vii:MCSD with Mucosal  
 144 Bleeding], as demonstrated by  
 145 ■ Pulmonary Capillary Wedge Pressure (PCWP) greater than 15,  
 146 and  
 147 ■ Mean Arterial Pressure (MAP) less than 90  
 148 ○ Abnormal pump parameters, such as significant and persistent increase  
 149 in pump power and low flow despite good blood pressure control  
 150 ○ Visually detected thrombus in a paracorporeal ventricular device (VAD)  
 151 ● The candidate is supported by one of the following treatments in the hospital:  
 152 ○ Intravenous anticoagulation (e.g. heparin)  
 153 ○ Intravenous thrombolytics (e.g. tPA)  
 154 ○ Intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban)

156 This status is valid for up to ~~1430~~ days from submission of the *Heart Status 3*  
 157 *Justification Form*.

159 After the initial ~~1430~~ days, this status can be extended by the transplant program  
 160 every 14 days by submission of another *Heart Status 3 Justification Form*. a  
 161 candidate's transplant program may extend the candidate's status every 90 days if  
 162 the candidate continues to meet the above criteria and the transplant program  
 163 submits another *Heart Status 3 Justification Form*.

### 165 **6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart** 166 **Failure**

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

- 171  
 172 1. Has been treated with at least one of the following therapies for at least 14  
 173 consecutive days, and requires ongoing treatment with at least *one* of the  
 174 following therapies:  
 175 ● Dobutamine greater than or equal to 5 mcg/kg/min  
 176 ● Dopamine greater than or equal to 4 mcg/kg/min

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- 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.

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

187

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

193

194 **6.1.C.vi Mechanical Circulatory Support Device (MCS) with Device**  
195 **Infection**

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

200

201

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

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

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

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

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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 placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias or receiving

217 continuous intravenous antiarrhythmic therapy, and has already been assigned to  
218 status 1 according to *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD)*  
219 *with Life Threatening Ventricular Arrhythmia* for 7 days. This status is valid for up to  
220 7 days from submission of *the Heart Status 3 Justification Form*.

221  
222 A candidate's transplant program may extend the candidate's status every 7 days if  
223 the candidate continues to meet the above criteria and the transplant program  
224 submits another *Heart Status 3 Justification Form*.

225  
226 #  
227