OPTN

Public Comment Proposal

Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

OPTN Heart Transplantation Committee

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Contents

Executive Summary	2
Background	4
Purpose of the Proposal	9
Proposal	9
Guidance Document	10
NOTA and Final Rule Analysis	12
Implementation Considerations	14
Post-implementation Monitoring	15
Conclusion	16
Policy Language	17
Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock	20

Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

Affected Policies:	*Policy 6.1.A.ii: Non-dischargeable, surgically implanted, non-endovascular biventricular support device* *Policy 6.1.C.vi: Mechanical Support Device with Infection* *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*
Sponsoring Committee:	*Heart Transplantation*
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Executive Summary

On October 18, 2018, the Organ Procurement and Transplantation Network (OPTN) implemented modifications to the adult heart allocation system.[1] The number of candidates in the most medically urgent status classification had grown substantially since the last major policy modifications implemented in 2006. Candidates at that status had higher waiting list mortality than the other statuses. In addition, there was substantial variation in waiting list mortality among the candidates within the highest status.

A primary goal of the 2018 modifications was "to better stratify the most medically urgent heart transplant candidates."[2] In order to do that, the OPTN Board of Directors (Board) approved the creation of more granular statuses to ensure that the sickest candidates have access to donor hearts first. The additional classifications and criteria were expected to also reduce the need for transplant programs to submit exception applications, which had also grown substantially since the 2006 changes.

Despite the modifications, the number of exception requests submitted following implementation has not decreased.[3] In 2019, the OPTN Thoracic Organ Transplantation Committee (the Heart Transplantation Committee was established on July 1, 2020. Hereafter, the Committee) agreed to develop guidance material to help educate the community about the use of exception requests.

While developing the guidance material, the Committee identified opportunities to clarify other parts of policy. This proposal contains policy and guidance changes designed to improve and clarify components of existing adult heart allocation policy.

- Policy: The Committee identified opportunities to amend certain policy language involving the timing of when certain hemodynamic data should be reported, and the number of extension days available for certain statuses and conditions. From time-to-time, members have raised questions about aspects of these policies since implementation in 2018. One of the policy changes will require the submission of new data elements.

[1] OPTN, Policy Notice, Additional Clarifications to the Adult Heart Allocation System Policy Language. Accessed April 13, 2020. https://optn.transplant.hrsa.gov/media/2538/thoracic_policynotice_201807_heart.pdf
[2] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, December 2016, p. 1.
[3] OPTN, *Proposal to Modify the Adult Heart Allocation System*, p. 2, and OPTN, *One Year Monitoring of the Heart Allocation Proposal to Modify the Heart Allocation System*, February 20, 2020, Table 14, p. 64. Note: Comparison based on exceptions per month for identified periods.

- Guidance: The proposed guidance seeks to clarify the types and amount of information needed for heart Regional Review Board (RRB) members to objectively evaluate an exception request for a candidate being supported by the temporary therapies of a Percutaneous Endovascular Mechanical Circulatory Support Device (MCSD) or an Intra-Aortic Balloon Pump (IABP). The guidance focuses on improving the usefulness of the information in the clinical narratives of such patients. The guidance document does not create or change OPTN policy.

Background

In December 2016, the OPTN Board approved changes to heart allocation policy.[4] The changes increased the number of adult heart statuses from three to six in order to better stratify the most medically urgent patients based on their conditions. The changes were implemented in October 2018, and represented the first major amendments to the adult heart allocation system in about a decade.

Prior to the OPTN Board's actions in December 2016, adult heart allocation policy categorized candidates as Status 1A (the most medically urgent), Status 1B, or Status 2. However, the number of candidates listed at Status 1A had ballooned since 2006, making it difficult to separate patient's by the severity of their illness. From July 31, 2006 to November 30, 2015, the number of candidates listed at the highest status, Status 1A, had grown from 58 to 376.[5] Candidates within the status had varying degrees of medical urgency as defined by waiting list mortality. As a result, the Committee recommended creating three additional heart statuses. In addition to creating the additional criteria, the Committee sought to define more specifically the qualifying criteria based on physiological characteristics.

While developing the allocation changes, the Committee found that within Status 1A candidates had disparate waiting list mortality rates based on specific medical conditions.[6] The Committee also determined that some candidate groups did not fall neatly into any of the statuses, and were forced to rely on exception requests to address their needs. Furthermore, the Committee used the policy changes to address the increased use of Mechanical Circulatory Support Devices (MCSD) by transplant programs.

Issues Identified With OPTN Heart Allocation Policy

In 2019, the Committee identified two policies from 2018 for additional amendments. The first involves *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*. The 2018 modifications require that a candidate's cardiac index be less than 2.2. L/min/m^2 within seven days of submission of the justification form[7]. Some transplant programs questioned why the date the cardiac index was measured was being associated with form submission instead of the start of inotropic therapy.[8] A transplant program submitted the following:

> *We did not feel it was in the patient's best interest to stop the inotropes, precipitate decompensation and risk worsening renal function or worse, cardiogenic shock and possible inability to recover [the candidate]*

Transplant program staff point out that inotrope administration is likely to stabilize a candidate's condition.[9] However, for the candidate to meet the cardiogenic shock requirements within seven days of form submission, the transplant program may need to remove the candidate from the inotropes.

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[4] OPTN, *Proposal to Modify the Adult Heart Allocation System*.
[5] IBID, p. 2.
[6] IBID, p. 2.
[7] OPTN, *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*.
[8] OPTN, *Modifications to the Adult Heart Allocation System: Frequently Asked Questions*, question 11, p. 7. Accessed June 28, 2020. https://optn.transplant.hrsa.gov/media/2688/adult-heart_revised-faq_20181008.pdf
[9] OPTN, *Proposal to Modify the Adult Heart Allocation System*, p. 11

Furthermore, the monitoring might require an invasive, right-heart catheterization procedure that puts the candidate at further risk. Possible risks include bruising where the catheter is inserted and potential for puncturing the vein during insertion and resulting excessive bleeding. Other, rarer complications can occur, including a pulmonary artery rupture, or even air leaking into the heart or chest area, that could lead to death.[10] In addition, for candidates who have been receiving inotropic therapy, the program may have to stop the therapy in order for the candidate to experience cardiogenic shock again.

A transplant program may choose not to perform a right-heart catheterization, or to attempt to wean a candidate from a medication in order to capture the cardiac index value if the candidate is in a stable condition. In such circumstances, a transplant program may consider requesting an exception or listing the candidate at another status. However, as previously discussed, relying on an exception request is not optimal for a candidate. First, it is up to the discretion of the transplant program if they want to submit an exception request. Second, exception requests must be approved by a RRB, increasing the potential that a candidate will not be assigned to the appropriate status. Likewise, listing a candidate at a lower status is not optimal either because the lower status may not provide the appropriate level of support needed by the candidate while awaiting transplant.[11] From October 18, 2018 through October 17, 2019, 240 candidates were added to the waitlist at Status 4 under the Inotropes without Hemodynamic Monitoring criteria.[12]

The Committee also considered increasing the initial qualifying and extension timeframes associated with assigning a patient to Status 4 as a result of *Policy 6.1.D.ii*. Such candidates can remain at the status for up to 90 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, the status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.

Based on the potential invasiveness associated with measuring cardiac index, the Committee considered how frequently the value is needed. In the post-implementation period evaluated in the one-year monitoring report, median days to transplant for Status 4 candidates was 262 days.[13] Under the pre-2018 allocation system, candidates considered similar to those in Status 4 now were allowed to remain at a similar status for an almost indefinite amount of time. For comparisons of pre- and post-implementation medical urgency statuses, Status 1B in the pre-implementation phase can be approximated with Statuses 4 and 5 in the post-implementation period.[14] Under the previous policy framework, a candidate who qualified for Status 1B was permitted to retain the status "for an unlimited period."[15] Moreover, a transplant program could extend a candidate's time at Status 1B without providing any new documentation. Several Committee members cited their own program's protocols establishing 180 days as the timeframe between right heart catheterizations.

If implemented, the proposed changes will require the OPTN to begin collecting new data fields on the Adult Heart Status 4 Justification Form. Currently, a transplant program must provide the dosage

[10] Johns Hopkins Medicine, *Right Heart Catheterization*, June 2020, Available at https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/right-heart-catheterization

[11] OPTN, Review Board Guidance for Hypertrophic/Restrictive (HCM/RCM) Cardiomyopathy Exception Requests, October 18, 2018, pp. 1 and 9, Available at https://optn.transplant.hrsa.gov/media/2637/thoracic_guidance_review_board_hcm_rcm_201806.pdf

[12] OPTN, *One-Year Monitoring of the Heart Allocation Proposal*, Table 2, p. 13.

[13] OPTN, "One-Year Monitoring Report on Revisions to the Adult Heart Allocation System," Presentation to Thoracic Organ Transplantation Committee, February 27, 2020, slide 14.

[14] OPTN, *One-Year Monitoring of the Heart Allocation Proposal*, p. 5.

[15] OPTN, *Proposal to Modify the Adult Heart Allocation System*, p. 43.

amount associated with the inotrope or inotropes administered to the patient. A program must also provide the values for the cardiac index and pulmonary capillary wedge pressure and the test dates of when the values were recorded. The test date provided for the cardiac index is validated to ensure it occurred within seven days prior to the date the justification form was submitted. If the provided test date is outside of the acceptable range, the transplant program will not be able to continue completing the justification form.

Under the proposed changes, a transplant program must still report the dosage associated with the inotrope or inotropes administered to the patient. However, a program will also need to provide the date indicating when the inotrope was first administered. The date will be validated against the test date provided by the program for the cardiac index to ensure the dates are within seven days of each other. The four additional data fields, a date field associated with each of the four listed inotropic treatments, are the only new data collection associated with the proposal. Similar date fields exist on the Adult Heart Status 3 Justification Form for candidates to qualify for *Policy 6.1.C.v: MCSD with Right Heart Failure*.

Also considered were the initial qualifying periods and extension periods associated with Policy *6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Devices.* A candidate assigned to this status and type of therapy initially qualifies for up to 14 days. A transplant program can extend a candidate using this criteria for up to an additional 14 days. The criteria for this therapy were created as part of the 2018 modifications. The Committee agreed to limit who could qualify for Status 1 when supported by a device that was not approved by the Federal Drug Administration (FDA) for use outside of a hospital to those with biventricular support devices.[16] The policy changes also created a status criterion in Status 2 for those candidates supported by Left Ventricular Assist Devices (LVAD) that are not approved by the FDA for use outside of the hospital. Both status criterion established 14 days as both the initial qualifying period and the extension period.

The Committee agreed that the Status 1 criterion would be more appropriate as seven days to distinguish it from the criterion established in Status 2. Furthermore, establishing the qualifying and extension periods as seven days better aligns it with the timeframes established in *Policy 6.1.A.i: Veno-Arterial Extra Corporeal Membrane Oxygenation (VA ECMO)*.

2018 Policy Changes Have Not Reduced Exception Request Volume

In addition to creating new statuses, the policy changes implemented in 2018 created additional qualifying criteria for the most urgent statuses.[17] Additional qualifying criteria were established for Status 1 under the VA ECMO criteria, Status 2 under the Percutaneous Endovascular MCSD and the IABP, and Status 3 under the multiple inotropes with hemodynamic monitoring criteria. Policy required that the therapies be used to treat cardiogenic shock.

The proposed policy changes were expected to better account for relative waiting list mortality rates of all candidate groups. This included those candidates forced to apply for policy exceptions, and would treat those patients more equitably.[18] However, data on the number of exception requests leading up to

[16] OPTN, *Proposal to Modify the Adult Heart Allocation System*, p. 12
[17] IBID, p. 10.
[18] OPTN, *Modifications to the Adult Heart Allocation System*, question 11, p. 7.

and following the policies changes suggest that there was no reduction in the use of exceptions requests.

During development of the 2018 policy changes, the Committee members agreed that a major problem of the allocation system was the use of too many exception requests.[19] For example, it was reported that between January 2014 and December 2015, transplant programs submitted a total of 5,878 Status 1A and Status 1B exceptions requests (5,340 Status 1A exception requests and 538 Status 1B exception requests). This works out to 245 exception requests per month based on 22 months.

Status 1A in the previous system is roughly equivalent to Statuses 1, 2, and 3 in the new allocation system. Statuses 4 and 5 in the new allocation system are roughly equivalent to Status 1B in the previous system. Information provided in the One-Year Monitoring Report of the new adult heart allocation system found that during the 14 months spanning September 2018 through October 2019, a total of 3,711 exception requests were submitted for candidates listed at adult Statuses 1, 2, 3, or 4. (Exception requests are not available for Status 5 under current policy). This works out to about 265 exception requests per month.

The current Committee was concerned by the lack of reduction in exception requests. On top of those concerns, the Committee members were also aware that during development of the previous policy, the initial and extension timeframes associated with certain temporary therapies were criticized for being too long and incentivizing transplant programs to leave their candidates on the temporary support longer than necessary.[20] In light of these concerns, they decided to focus on addressing the use of Status 2 exception requests. The members agreed that clarifying what information should be provided as part of an exception request could be beneficial without having to revise policy.

This is particularly true regarding Status 2 exception requests. For example, in the year following implementation, the percentage of adult heart waiting list additions qualifying by an exception at time of listing was greatest for adult Status 2 (**Table 1**).[21] Of the 722 candidates listed at Status 2, 227 (31%) qualified by exception rather than the criteria established in policy.[22]

Table 1: Adult Heart Waiting List Additions With an Exception for Statuses 1 – 4 at Listing Post-implementation (October 18, 2018 – October 17, 2019)

Adult Status	Number of Waiting List Additions With an Exception	Total Number of Waitlist Additions	Percentage of Waitlist Additions by Exception
1	32	168	19.05%
2	227	722	31.44%
3	86	483	17.81%
4	249	1,581	15.75%

Concerned by what was perceived as a still large volume of exception requests for listing at Status 2,as opposed to qualifying by the criteria established in policy, the Committee looked more closely at the reasons for exceptions. During August 2019, Committee leadership reviewed the redacted clinical

[19] OPTN, *Proposal to Modify the Adult Heart Allocation System*, p.2
[20] OPTN, *Proposal to Modify the Adult Heart Allocation System*, p. 11
[21] OPTN, *One Year Monitoring of the Heart Allocation Proposal,* Table 2, p. 12.
[22] IBID, Table 2, p. 12.

narratives of more than 200 adult heart Status 2 exception requests submitted from June 1 through July 31, 2019. They included both initial exception requests and extension exception requests.

While the review only examined thirty days' worth of exception requests and was mainly exploratory in nature, some trends were identified, suggesting transplant programs could benefit from a guidance document. The review found some requests were lacking certain hemodynamic data that the reviewers believed was baseline information that should have been included, while others contained no hemodynamic data at all. Other requests included clinical narratives that provided hemodynamics that were not appropriate based on policy for the status being requested, such as systolic blood pressure greater than 90 mmHg or pulmonary capillary wedge pressure less than 15 mmHg. Furthermore, some of the clinical narratives reviewed met the criteria associated with hypertrophic/restrictive cardiomyopathy or adult congenital heart disease for which guidance exists[23] but did not reference the guidance and potentially missed an opportunity for the candidate to qualify for the status being requested.

The reviewers expressed concern that the information being provided in the exceptions they reviewed was not adequate for a hypothetical review board member to make a decision. While exceptions exist to address those instances where a candidate does not meet the criteria established in policy, the transplant program is supposed to use objective evidence to demonstrate that a candidate has at least the same medical urgency as other candidates in that status, and the same potential for benefit. The reviewers believed that programs were not providing enough information or the correct types of information to demonstrate their candidate had the same medical urgency.

In evaluating exception requests, the RRB members are tasked with determining whether a "candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status."[24] When submitting an exception request, a transplant program is supposed to demonstrate the similar urgency and potential benefit using acceptable medical criteria.[25] However, the policy does not define what constitutes acceptable criteria.

Nonetheless, RRBs approved more than 90 percent of the Status 2 exception requests submitted in the year following implementation of the new allocation policy.[26] The lack of guidance pertaining to what information should be included in the narrative likely results in wide variability of the detail and appropriateness of requests. This makes it difficult for RRB members to make consistent decisions.

Members of the Committee indicated that the one-year monitoring report findings reinforced the Committee's efforts addressing Status 2 exceptions for candidates supported by Percutaneous Endovascular MCSD and IABP through a guidance document that helps to: standardize exception requests for Status 2 candidates supported by these temporary therapies; clarify criteria indicative of VAD contraindications; ensure that patients are only placed on Percutaneous Endovascular MCSD or IABP when those therapies are most appropriate; and provide structure for clarity needed by RRB members to evaluate.[27]

[23] OPTN, *Review Board Guidance for Hypertrophic/Restrictive (HCM/RCM) Cardiomyopathy Exception Requests*, and OPTN, *Review Board (RB) Guidance for Adult Congenital Heart Disease (CHD) Exception Requests*.
[24] OPTN, *Policy 6.4: Adult and Pediatric Status Exceptions.*
[25] OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet℠ October 29, 2019.
[26] OPTN, *One-Year Monitoring of the Heart Allocation Proposal*, Table 16, p. 66.
[27] OPTN, Thoracic Organ Transplantation Committee, meeting summary, February 27, 2020.

Purpose of the Proposal

The Committee has carefully monitored the impacts resulting from the allocation policy changes implemented in 2018. Based on those changes, the Committee identified opportunities to better operationalize existing policy through clarifications and amendments, including changes that could better align policies based on the intended medical urgencies.

In addition to the policy clarifications, , the Committee concluded that addressing the use of exceptions associated with Status 2 candidates being treated with Intra-Aortic Balloon Pumps or Percutaneous Endovascular Mechanical Circulatory Support Devices would likely have a substantial impact towards aligning the behavior of the transplant programs and regional review boards more closely with the adult heart policy. The proposed guidance document is designed to provide transplant program staff who prepare exception requests and regional review board members who review the requests with more effective practices regarding the types of information and level of detail that should be included in any request. The Committee's intent is to establish a standard or baseline of information that would be reasonably expected to describe a candidate's clinical status. Such a standard, consistently applied, should minimize the differences currently found across the requests and improve the ability of the regional review boards to consistently apply policy across the requests.

Proposal

In an effort to ensure that adult heart allocation policy treats candidates with similar medical urgency equally, the Committee proposes the following changes:

Timing of Obtaining Hemodynamic Data Associated With *Policy 6.1.D.ii: Inotropes Without Hemodynamic Monitoring*

Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring requires that a candidate have a cardiac index of less than 2.2 L/min/m^2 *within 7 days prior to submission of the Heart Status 4 Justification Form* [emphasis added].[28] The heart transplant community has questioned associating the timing of obtaining the cardiac index to submission of the form. The Committee agreed that a policy change was appropriate to clarify that a stable candidate did not need to undergo additional hemodynamic testing to obtain the value.

This proposal removes the policy language associated with submission of the Adult Heart Status 4 Justification Form as the baseline for measuring when a candidate's cardiac index met the requirement. In its place, the following language is proposed "Cardiac index of less than 2.2 L/min/m^2 within 7 days prior *to inotropic administration or while on inotrope infusion as specified* [emphasis added]" by subsequent criteria in the policy. The Committee members agreed that their intent in proposing the change is to indicate to the transplant programs that a candidate should not be weaned from inotropes in order to perform a right heart catheterization to prove that the candidate had a cardiac index indicating cardiogenic shock.[29]

[28] OPTN, *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*.
[29] Meeting Summary for April 17, 2020 meeting, OPTN, Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/3783/20200417_thoracic_meeting-summary.pdf (accessed June 6, 2020)

Additionally, this proposal extends the length of both the initial qualifying period and the extension from 90 to 180 days. Extending the timeframe results in less invasive testing of a stable candidate who may be waiting for a transplant for some time.

If approved, the policy changes will result in the collection of additional data fields. The data fields will indicate the date associated with the inotrope administration. The dates will be used to validate that the cardiac index value was measured within seven days of inotrope initiation, as opposed to within seven days prior to form submission as currently established in policy. The Data Advisory Committee (hereafter, DAC) reviewed the data fields in their role as an operating committee with responsibility for all data collection activity. The DAC members did not have any concerns about the proposed data fields.

Aligning Extension Timeframe for *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* with Other Status 1 Conditions

A candidate listed at Status 1 under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* is eligible to stay at the status for up to 14 days under the initial application. The candidate's stay can be extended every 14 days by submission of another extension form. Candidates are not required to meet any additional criteria in order to extend under this criteria. This proposal will limit the initial qualifying period and the extension period to up to seven days for a candidate assigned to Status 1 by a non-dischargeable, surgically implanted, non-endovascular biventricular support device. Limiting the initial and extension timeframes more closely aligns this criterion with the timeframes established in *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)*.

The Committee sought to make the initial qualifying timeframes and extension timeframes consistent within the Status 1 criteria. Median days to transplant for Status 1 candidates was four days during the post-implementation period of October 18, 2018 through October 17, 2019.[30] During that time, 22 candidates were added to the waiting list under Policy 6.1.A.ii, while 102 candidates were added under the VA ECMO criteria.[31]

Reordering Listing of Evidence of Device Infections

In order to better clarify the policy, the Committee is proposing to rearrange the order of the table identifying the evidence of device infection associated with *Policy 6.1.C.vi: Mechanical Support Device with Infection*. It was recommended that the criterion of positive culture of material from the pump pocket of an implanted device should follow the criterion referring to debridement of the driveline. Then the two bacteremia-specific infections would be grouped together.

Guidance Document

A goal of the 2018 Modifications to the Adult Heart Allocation System policy changes was to reduce the number of exceptions by better accommodating the clinical scenarios addressed in policy. Reliance on

[30] OPTN, *One-Year Monitoring of the Heart Allocation Proposal to Modify the Heart Allocation System*, February 20, 2020, Table 9, p. 48.
[31] OPTN, *One-Year Monitoring of the Heart Allocation Proposal to Modify the Heart Allocation System*, Table 2, p. 12.

exception requests is not optimal for the patient. First, similar candidates may be treated differently because the decision to submit an exception request is made by the individual transplant program. Programs may use different criteria when making such decisions. Second, an exception request must be reviewed and approved by a regional review board, resulting in the possibility that the request will be denied. Additionally, the lack of clear and direct guidance regarding the use of exceptions may result in variability from reviewer to reviewer and region-to-region, introducing another level of complexity for the candidate's request.

However, as stated in the Background section, monitoring reports following implementation found that the anticipated reduction in exception request volume had not occurred. Moreover, the majority of the exception requests submitted under the new policy are being approved by the regional review boards. Reasons why the number of exception requests have not decreased may include:

- The community is still familiarizing itself with the new policy
- The community has found a pathway to circumvent the standard criteria
- The community has found some of the criteria more stringent
- The new policy still does not adequately accommodate most clinical scenarios
- The regional review board members are unsure of how to interpret the new policy and so are reluctant to deny exception requests
- The community is using temporary support devices in ways that were not considered when the new policy was developed

The Committee drafted the guidance document with the goal of assisting heart transplant programs to complete exception requests more uniformly for status 2 candidates who are supported by Percutaneous Endovascular MCSD and IABP. The guidance is also intended to help the RRBs evaluate exception requests by identifying certain standard information that should be included with each request.

The following scenario to demonstrate what they believe would constitute an appropriate level of detail in a clinical narrative as part of an initial exception request. The example is meant for illustrative purposes only, and does not reflect an actual patient.

> *Our patient is a 62 year-old male with ischemic cardiomyopathy, ejection fraction (EF) 10%, who was placed on an IABP on May 15 for refractory cardiogenic shock demonstrated by cardiac index (CI) 1.8, pulmonary capillary wedge pressure (PCWP) 18, and systolic blood pressure (SBP) 95 and intermittent angina on milrinone 0.5 mcg/kg/min. After implantation his PCW dropped to 12, SBP rose to 110 and CI rose to 2.2 and has had no further angina. He was listed Status 2 on May 16. His current hemodynamics are right atrium (RA) 5-8, pulmonary artery (PA) 40s/20s, PCWP 12-15, and CI 2.1-2.4. We are requesting this exception to the SBP under 90 because attempts to increase inotropes worsened angina and more aggressive diuresis or GATA4, Mef2c, and Tbx5 (GMT) resulted in worsened renal function.*

The following is what an appropriate and descriptive clinical narrative might appear like if the fictional candidate's program was to submit an extension request:

> *In the last 48 hours, we did not attempt to wean from the IABP as the patient remains in persistent cardiogenic shock as evidenced by worsening CI to 1.8 on full IABP support as well as decline in mixed venous oxygen saturation SVO2 to take 48%. At this time, we are worried that patient is not a candidate for durable LVAD due to inability to take warfarin due to the current gastrointestinal (GI) bleeds.*

The Committee expects the guidance will assist transplant programs to demonstrate that a candidate has both the medical urgency and potential for benefit comparable to that of other candidates at this status.[32] The guidance document describes the expected level of detail.

NOTA and Final Rule Analysis

The 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 for cadaveric organs."[33] The OPTN is providing the public with the opportunity to comment on these proposed policy changes in accordance with NOTA[34] and the Final Rule.[35]

In addition, because it will require the submission of official OPTN data that are not presently collected by the OPTN, the Committee submits the following proposal for Board consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall…submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[36] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients."[37]

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," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment[38]** because the policy modifications were made to better align candidates' medical urgencies with policy and clarify that programs are not required to stop inotropic treatment to obtain a cardiac index value.
- **Seeks to achieve the best use of donated organs[39] by** ensuring organs are allocated and transplanted according to medical urgency. Because the underlying goal of the changes to adult heart allocation policy was to ensure that the most medically urgent candidates are prioritized, these policy changes further that goal by refining the requirements for candidates to qualify for the higher urgency statuses.

[32] OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet℠ October 29, 2019.
[33] 42 C.F.R. §121.4(a)(1).
[34] 42 U.S.C. §274(a)(2)(B).
[35] 42 C.F.R. §121.4 (a), (b)(1), and (e)(2).
[36] 42 C.F.R. §121.11(b)(2).
[37] 42 C.F.R. §121.11(a)(1)(ii).
[38] 42 C.F.R. §121.8(a)(1).
[39] 42 C.F.R. §121.8(a)(2).

- **Is designed to…promote patient access to transplantation[40] by** giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal refines status criteria to ensure that candidates that are medically similar to each other have an equitable opportunity for transplant based on their urgency status.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[41] and it is specific to an organ type, in this case heart.[42]

The proposal outlined in this briefing paper 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. This proposal is not anticipated to impact the number of organs recovered but not transplanted.
- Shall be designed to avoid futile transplants. This proposal is not anticipated to result in transplantation of recipients that are unlikely to have positive post-transplant outcomes.
- Shall be designed to promote the efficient management of organ placement. This proposal is not anticipated to affect the costs and logistics of procuring and transplanting organs.
- Shall not be based on the candidates place of residence or place of listing, except to the extent required [by the aforementioned criteria]. This proposal is not based on the candidate's place of residence or place of listing.

The OPTN issues the guidance for the operation of the OPTN.[43] This guidance will support the operation of the regional review boards by assisting the reviewers with evaluating exception requests. The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including "reducing inter-transplant program variance."[44] This guidance document will assist in reducing inter-transplant program variance in the performance indicators initially adopted by the Board when it modified the adult heart allocation system. These performance indicators include exception requests stratified by medical urgency status.[45]

Consideration of Potentially Disadvantaged Groups and Transition Procedures

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised to ensure that those waiting for transplant are treated "no less favorably than they would have been treated under previous policies".[46] The Committee did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors. The members considered the potential impact of reducing a candidate's stay from 14 days to seven days under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device*. The Committee agreed that the shorter timeframe was appropriate based on the medical urgency associated

[40] Ibid.
[41] 42 C.F.R. §121.8(a)(3).
[42] 42 C.F.R. §121.8(a)(4).
[43] 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.
[44] 42 C.F.R. §121.8(b)(4)
[45] OPTN Briefing Paper: Proposal to Modify the Adult Heart Allocation System. December 2016. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf (accessed on June 24, 2020).
[46] 42 C.F.R. § 121.8(d).

with Status 1 candidates, as well as the information that the median wait to transplantation was four days for Status 1 candidates.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Transplants programs will need to educate their personnel on the details associated with the policy modifications and the availability of the guidance document. Transplant programs may need to update their training protocols related to the completion of adult heart status justification forms related to initial, extension, and exception applications. Program staff may want to provide more substantive information detailing the reasons a candidate meets the clinical criteria associated with the adult status criteria than has previously been provided. The update may require closer interaction with the physicians and other clinical care providers. Programs with adult status 1 patients who meet the criteria for non-dischargeable, surgically implanted, non-endovascular biventricular support device will need to more frequently update their adult heart status 1 justification forms in order to extend their candidates at the status.

Transplant programs assisting adult heart Status 4 candidates who are meeting the criteria for inotropes without hemodynamic monitoring will need to provide the date the candidate's inotrope administration started in order to validate that the cardiac index value was collected within seven days of the start of inotrope administration. A transplant program will provide the date when inotrope administration was started on the Adult Heart Status 4 Justification Form.

Operations affecting Histocompatibility Laboratories

This proposal is not expected to affect the operations of Histocompatibility Laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not expected to affect the operations of Organ Procurement Organizations.

Operations affecting the OPTN

Programming changes are required as part of the proposal. First, four new data fields will be collected indicating the date of inotrope initiation. A transplant program will be required to report the date associated with the initiation of the following intravenous inotropes:

- Dobutamine
- Dopamine
- Epinephrine
- Milrinone

The date information will be used to validate that the cardiac index was measured within seven days of inotrope administration.

Currently, similar dates are already captured on the justification forms associated with *Policy 6.1.C.v: Mechanical Circulatory Support Device with Right Heart Failure*. Transplant programs are already

required to enter the dosage associated with the therapy being used. Under the policy change, programs would also have to enter the date the inotrope therapy was initiated. Transplant program staff can enter the date in a MM/DD/YYYY format. In an effort to promote data consistency, transplant programs also have the ability to use a calendar link programmed into the forms to select the date. This approach should limit formatting issues associated with the dates.

In addition, changes are need to the heart justification forms and to the timing associated with the extension forms. The changes will also necessitate special circumstances for managing the justification forms that were in place prior to the implementation of these policy changes. This is estimated as a large IT effort based largely on handling the 'in-flight' forms and required database modifications.

Projected Fiscal Impact

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. As part of the proposed changes to Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring transplant programs must provide the date of inotrope initiation for up to four inotropes. The dates will be used as a factor in determining whether the candidate is eligible for listing at Status 4 under this criterion. Currently, the OPTN does collect the initiation dates for this criterion, although it collects this information as part of Policy 6.1.C.v: Mechanical Circulatory Support Device with Right Heart Failure. The collection of new OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB). The OMB approval process may impact the implementation timeline.

Minimal or no expected fiscal impact for OPOs, transplant hospitals, or histocompatibility labs.

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."[47]

The proposed language will not change the current routine monitoring of OPTN members. Site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in UNet℠ 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."[48] On October 18, 2018, the OPTN implemented substantial changes to the adult heart allocation system. The new policy clarifications will be monitored in conjunction with and on the same timeline as the October, 2018 system changes. Specific additions to the monitoring plan will include the changes in the

[47] 42 C.F.R. §121.8(a)(7)
[48] 42 C.F.R. §121.8(a)(6)

number of Status 1 Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device (Policy 6.1.A.ii) and the number of Status 4 Inotropes without Hemodynamic Monitoring (Policy 6.1.D.ii) initial and extension requests. As sample size permits, the waiting list mortality rate for these criteria for Status 1 and Status 4 candidates may be reported and compared based on pre- and post-policy clarification date. To monitor the guidance document, the number of transplants by adult heart status and exception status will be compared based on pre- and post- implementation of the guidance. As sample size permits, the waiting list mortality rate for Status 2 candidates will be compared pre- and post-implementation of the guidance. The OPTN and SRTR contractors will work with the Committee to define any additional analyses requested for monitoring.

Conclusion

This proposal is part of an effort by the Heart Transplantation Committee to address issues identified when the adult heart allocation system changes were implemented in October 2018. The changes proposed for *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring* intend to ensure that the condition of a stable patient is not put in jeopardy to obtain a cardiac index measurement, and that the initial and extension qualifying periods are appropriate. The Committee members also agreed that the initial and qualifying periods for *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* should be shortened to reflect the high medical urgency of such candidates and the median length of time they remain in the status before being transplanted. Finally, the Committee sought to clarify OPTN policy by reordering the symptoms identified in MCSD and device infections.

Adult heart transplant programs should consider this guidance when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. RRB members are encouraged to consult this resource when assessing exception requests on behalf of Status 2 candidates supported by a under Percutaneous Endovascular MCSD or by an IABP.

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 Adult Status Assignments and Update Requirements

6.1.A Adult Heart Status 1 Requirements

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 ~~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.*

6.1.C Adult Heart Status 3 Requirements

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

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

Table 6-1: Evidence of Device Infection

If the candidate has evidence of:	Then this status is valid for up to:
Erythema and pain along the driveline, with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and *either*: • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the driveline exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the driveline exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Positive culture of material from the pump pocket of an implanted device	90 days from submission of *the Heart Status 3 Justification Form*.
Bacteremia treated with antibiotics	42 days from submission of *the Heart Status 3 Justification Form*.
Recurrent bacteremia that recurs from the same organism within four weeks of completing antibiotic treatment to which the bacteria is susceptible	90 days from submission of *the Heart Status 3 Justification Form*.
~~Positive culture of material from the pump pocket of an implanted device~~	~~90 days from submission of *the Heart Status 3 Justification Form*.~~

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

6.1.D Adult Heart Status 4 Requirements

6.1.D.ii Inotropes without Hemodynamic Monitoring

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

1. Cardiac index of less than 2.2 L/min/m^2 within 7 days prior to ~~submission of the *Heart Status 4 Status Justification Form*~~ inotropic administration or while on inotrope infusion as specified below
2. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
3. Requires at least *one* of the following intravenous inotropes:
    - Dobutamine greater than or equal to 3 mcg/kg/min
    - Milrinone greater than or equal to 0.25 mcg/kg/min
    - Epinephrine greater than or equal to 0.01 mcg/kg/min
    - Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to ~~90~~180 days from submission of *the Heart Status 4 Justification Form*. After the initial ~~90~~180 days, this status can be extended by the transplant program every ~~90~~180 days by submission of another *Heart Status 4 Justification Form*.

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Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock

Recommendations

The following information provides useful guidance for transplant program staff responsible for completing the clinical narrative portion of an initial exception request or an extension exception request on behalf of a candidate to be assigned at status 2. Transplant programs are expected to demonstrate that a candidate has both the medical urgency and potential for benefit comparable to that of other candidates at this status.[49] The information may also be useful guidance for Heart Regional Review Board (RRB) members who are asked to approve upgraded listing urgency by exception for adult heart candidates.

The guidance is designed to serve as a template for transplant program staff who are responsible for completing the clinical narrative portion of exception requests. The Committee realizes the guidance will not address all cases, but believes it will be a useful and practical tool. In addition, the guidance is intended to provide RRB members with a roadmap to certain, useful information necessary for making informed decisions.

The guidance is organized in three sections: a clinical description of the patient, factors impacting the program's attempt to wean the candidate, and applicable contraindications to a VAD. The Thoracic Committee identified these as important components for any description of why the temporary therapies of Percutaneous Endovascular MCSD or IABP was used to treat a candidate's cardiogenic shock. It is the Committee's intention that the list of clinical criteria in this section should serve as evidence that the candidate remains with persistent hemodynamic instability. When completing the clinical narrative of an exception request, transplant program staff should be submitting clinical measurements and not just indicating the presence or absence of a condition.

TEMPLATE

Section 1: Characterization of the Patient

Candidate (Waiting list ID#) is a (age) year old (male/female) with (Dilated/Ischemic/Restrictive) Cardiomyopathy who is status post (S/P) Percutaneous Endovascular MCSD or IABP on (implant date) in this transplant program's Intensive Care Unit on Inotropes (provide agents and dose) and Pressors (provide agents and dose). Patient has been listed as a Status (1/2/3/4/5/6) since _____

Current hemodynamics are as follows (If a Swan-Ganz catheter is available,):

Right Atrium (RA):	
Pulmonary Artery (PA):	
Pulmonary Capillary Wedge Pressure (PCWP):	
Cardiac Index (CI):	

[49] OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet℠ October 29, 2019.

We are requesting this exception for _ (specify data item)_____
because _____

Section 2: Inability to Wean Candidate

In the last 48 hours, we did not attempt weaning from Percutaneous Endovascular MCSD or IABP as the candidate remains in persistent cardiogenic shock as evidenced by: (provide the values for one or more items)

Hypotension Mean Arterial Pressure (MAP):	
Reduced Cardiac Index (CI):	
Elevated PCW:	
Low $SvO_{2\ or}$ PA sat	
Worsening End Organ Function:	
Requiring increasing doses of inotropic agents or pressors:	
Ventricular Tachycardia (VT):	
Other:	

Section 3: Contraindications to LVAD

The following should be considered as general information that might be expected when describing why a patient is not a candidate for durable LVAD Support (extension only).

1. Severe Right Heart Failure (RHF)
    a. Echo: Severe TR; TASPE < 7.5mm; RVEF < 20%; RV/LV size > 0.75
    b. Hemodynamic: RA:PCW > 0.54; RVSWI < 250; PAPi < 1
2. Surgical Contraindications
    a. Mechanical Aortic Valves (AV)
    b. Mechanical Mitral Valves (MV)
    c. Small Left Ventricle (LV) Cavity
    d. Left Ventricular Thrombus
    e. VSD
    f. Body size BSA < 1.1
    g. Other: (Describe)
3. Need for Multi-organ Transplant
    a. Renal
    b. Liver
4. Blood Dyscrasias
    a. Thrombocytopenic
    b. Hypercoagulable
    c. Contraindication to Warfarin
5. Active Co-morbidity
    a. Infection
        i. Date: _(mm/dd/yyyy)
        ii. Site:_____
        iii. Culture:_____
    b. Recent CVA
        i. Date: _(mm/dd/yyyy)

   c. Bleeding
      i. Date: _(mm/dd/yyyy)
      ii. Site:_____
6. Re-current Refractory Ventricular Arrhythmias
7. Other:_____

Note: It is recommended that requesting programs not rely solely on patient preference when submitting an extension exception request to maintain a candidate at Status 2.

Conclusion

Adult heart transplant programs should consider this guidance when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. RRB members are encouraged to consult this resource when assessing exception requests on behalf of Status 2 candidates supported by a under Percutaneous Endovascular MCSD or by an IABP.

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