OPTN

Public Comment Proposal

Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN Heart Transplantation Committee

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Contents

Amend Adult Heart Status 2 Mechanical Device Requirements

Affected Policies:	*6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device* *6.1.B.v Intra-Aortic Balloon Pump (IABP)*
Sponsoring Committee:	*Heart Transplantation*
Public Comment Period:	*July 27, 2023 – September 19, 2023*

Executive Summary

The Organ Procurement and Transplantation Network (OPTN) Board of Directors approved substantial modifications of the adult heart allocation policy in December 2016.[1] The changes, which were implemented in October 2018,[2] created more granular statuses based on waitlist mortality and other clinical factors.[3] Since implementation, assignments to adult heart status 2 by use of the intra-aortic balloon pump (IABP) criterion have accounted for nearly 45 percent of all status 2 waitlist additions.[4] However, data analysis indicates the waitlist mortality rates of such candidates are less aligned with those of candidates assigned to other status 2 criteria.[5]

As a result, the OPTN Heart Transplantation Committee (the Committee) has developed a policy proposal to better align the eligibility criteria associated with the use of an IABP with the other status 2 requirements and properly align the waitlist mortality rates. Specifically, the Committee proposes modifying the status 2 eligibility criteria by requiring programs to demonstrate a failure of inotropic therapy before proceeding to the placement of an IABP or percutaneous endovascular mechanical circulatory support device (MCSD). The Committee also proposes new requirements for programs to extend a candidate's assignment in status 2 with an IABP or percutaneous endovascular MCSD. This includes demonstrating the candidate failed weaning from the device while still receiving inotropic therapy.

[1] *Proposal to Modify the Adult Heart Allocation System*, OPTN Thoracic Organ Transplantation Committee, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf (accessed June 22, 2023).
[2] "Modify Adult Heart Allocation." Public Comment, Second Round. OPTN Thoracic Organ Transplantation Committee. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-adult-heart-allocation-2016-2nd-round/
[3] *Proposal to Modify the Adult Heart Allocation System*.
[4] "OPTN Descriptive Data Request, "Three-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Prepared for OPTN Heart Transplantation Committee Meeting, October 11, 2022, https://optn.transplant.hrsa.gov/media/hx1pr13a/data_report_heart_committee_3yr_rpt1_508_compliant.pdf (accessed June 22, 2023)," p. 15.
[5] "Three-Year Monitoring of Heart Allocation Proposal," p. 31.

Purpose

The purpose of this proposal is to revise the eligibility criteria for IABPs and percutaneous endovascular MCSDs within adult heart status 2 to better reflect the high-level of medical urgency associated with the other adult heart status 2 criteria. To accomplish this, the Committee proposes requiring transplant programs to demonstrate that inotropic therapy was administered to manage the candidate's condition, and the therapy failed prior to the program implanting an IABP or percutaneous endovascular MCSD. The proposal also modifies the status extension requirements by requiring the program to demonstrate the candidate failed weaning from either of the devices while on inotropic therapy.

It is important to note, the proposed requirements involving inotropic therapies would not be a requirement for candidates experiencing an emergency situation in which an IABP or percutaneous endovascular mechanical support device is needed to save the life of the candidate. Such clinical conditions are addressed in current OPTN heart allocation policy and are not being modified.

Background

In December 2016, the OPTN Board of Directors approved a comprehensive revision of adult heart allocation policy. The changes, which were implemented in October 2018, were the response to several issues that had arisen since the last major policy changes in 2006. Chiefly among the concerns was that too many patients were assigned to the highest medical urgencies, despite the patients having vastly disparate waiting list mortality risks.[6] Other disadvantages were also identified including the high volume of exception requests for registering candidates on the waiting list and how candidates were diagnosed and treated.

In response, heart allocation policy was amended to better stratify patients based on medical urgency by creating additional, and more granular statuses.[7] In addition, standardized definitions were created for certain clinical conditions, such as cardiogenic shock, to make their diagnosis more consistent.[8] The types of therapies used to support candidates for heart transplant were also given greater attention in the new policies, especially the use of mechanical circulatory support devices. The policy included an increased number of statuses that addressed the changes in therapies and devices, with a goal that transplant programs would be less likely to rely on exception requests to assign their candidates to the appropriate medical urgency.

While it is generally acknowledged that the policy changes implemented in October 2018 have been successful in improving the waitlist mortality rates of the higher urgency statuses, improvements can still be made to disincentivize the use of therapies and/or mechanical devices to obtain higher urgency listings not matching the patient's clinical condition. An increase in the use of IABPs, a catheter device that is inserted into the aortic artery that inflates and deflates to assist the heart in pumping blood, has accounted for 45 percent of all status 2 waitlist additions since implementation. Prior to implementation, IABP accounted for only 13 percent of all candidates on the waitlist.[9] Implanting an

[6] *Proposal to Modify the Adult Heart Allocation System*.
[7] *Proposal to Modify the Adult Heart Allocation System*.
[8] Ryan R. Davies et al., "The New United States Heart Allocation Policy: Progress Through Collaborative Revision," *The Journal of Heart and Lung Transplantation*, Vol. 36, No. 6, June 2017, pp. 595-96, DOI: https://doi.org/10.1016/j.healun.2017.03.010.
[9] "Three-Year Monitoring of Heart Allocation Proposal," p. 22.

IABP is considered an effective therapy for treating temporary cardiogenic shock, a condition that if not treated quickly can be life-threatening or lead to organ failure or brain injury.[10]

The change in heart allocation placed the candidates with the highest waitlist mortality rates in status 1, with each subsequent status having lower waitlist mortality rates. This system placed candidates with an IABP in status 2, the second highest status for candidates on the waitlist. Concerns over potential unintended consequences of including IABPs in status 2 were raised during both public comment periods as the proposal was shared for feedback. Commenters at that time stressed that including IABPs under status 2 would incentivize the use of an IABP by transplant programs in an attempt to list their candidates in a higher status.[11] The commenters emphasized that IABPs are considered easier to insert than other devices that would qualify a program's candidate for a lower status.[12] In response to this feedback, the Committee attempted to make IABP status 2 qualifications more stringent by including stricter criteria to qualify and extend for status 2 with an IABP following public comment.[13]

In their post public-comment review of the proposal, the Committee discussed the use of an IABP as a criterion for status 2 and whether it should be assigned to a lower status. After examining the waitlist mortality data for candidates with an IABP and comparing it to other status 2 and status 3 devices, the data showed the mortality rates of candidates with an IABP was comparable to other status 2 criteria at that time.[14] Therefore, the Committee felt it would be inappropriate to remove the IABP from status 2.[15] The new heart allocation policy with six statuses was implemented in 2018.

Concerns about using an IABP to gain access to a higher status continued post-implementation. In a 2018 white paper, the OPTN Ethics Committee acknowledged this type of scenario potentially occurring within heart allocation.[16] While the white paper focused on several aspects of the transplant process, heart listing criteria was noted for providing an opportunity for manipulation due to the use of therapeutic measures to assess disease severity. By dividing patients into statuses based on therapeutic intervention and devices "an unintended consequence of this approach is that a physician can raise the priority status of a patient by instituting more advanced therapeutic measures even in the absence of true medical necessity."[17]

A 2023 study examined 3,638 status 2 candidates listed between 2018, and 2021. Of those candidates, 46 percent (1,676) were listed under the IABP criterion.[18] The waitlist mortality of the examined IABP candidates was lower than candidates on non-dischargeable surgically implanted non-endovascular left ventricular assist devices (LVAD), total artificial heart (TAH), biventricular assist devices (BiVAD), right

[10] "What is Cardiogenic Shock?," *National Heart, Lung, and Blood Institute; National Institutes of Health; U.S. Department of Health and Human Services, https://www.nhlbi.nih.gov/health/cardiogenic-shock#:~:text=If%20not%20treated%20quickly%2C%20cardiogenic,organ%20failure%20or%20brain%20injury. (accessed June 22, 2023).*

[11] *Proposal to Modify the Adult Heart Allocation System*, 23.

[12] *Proposal to Modify the Adult Heart Allocation System*, 23.

[13] *Proposal to Modify the Adult Heart Allocation System*, 13.

[14] *Proposal to Modify the Adult Heart Allocation System,* 24.

[15] *Proposal to Modify the Adult Heart Allocation System,* 23 and 24.

[16] *Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies*, OPTN Ethics Committee, June 2018, https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf.

[17] *Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies*, 1.

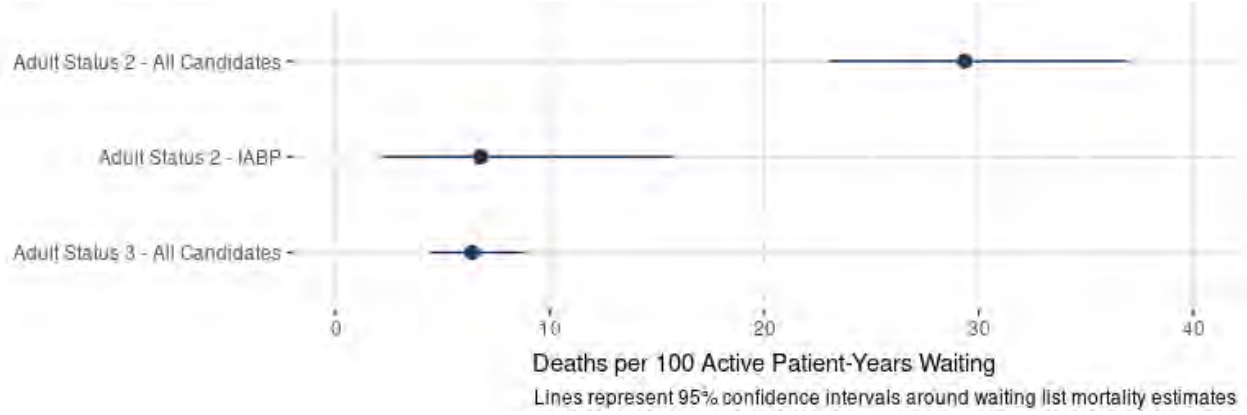
[18] Thomas C. Hanff et al., "Heart Waitlist Survival in Adults with an Intra-Aortic Balloon Pump Relative to Other Status 2, Status 1, and Inotrope Status 3 Patients," *The Journal of Heart and Lung Transplantation,* vol. 42,3 (2023): 370. Doi:10.1016/j.healun.2022.10.010.

ventricular assist devices (RVAD), or ventricular assist devices (VAD); the other status 2 criteria.[19] The status 2 group examined in the study had a median of 6 days to transplant, with 82 percent of the candidates examined receiving a transplant within 28 days.[20] This study also clearly demonstrated that waitlist mortality rates for candidates listed under the IABP criteria were more aligned with status 3 candidates than other status 2 mechanical devices.

Another study suggests the increase in candidates on IABP at time of transplant is due to the lack of "therapeutic escalation strategies-for example, continued inotropic support vs IABP…"[21] As stated by a different study, "there are likely patients listed as status 2 with an IABP that could have previously been managed with the low doses of inotropes."[22] Inotropes are medicinal drugs administered intravenously that assist the heart muscles in pumping blood. A third study examined the decrease in all candidates on inotropes. The study explained this decrease by suggesting transplant programs are now using alternative mechanical therapies, primarily IABP, to garner a higher priority status for a candidate.[23] The same study simply stated, "the hemodynamic requirements are not limiting use of this treatment [IABP] as much as expected."[24]

In October of 2022, the Committee reviewed the three-year monitoring report of the heart allocation system. The report showed a 16 percent increase in IABP usage, and the waitlist mortality rates of IABP candidates since the 2018 implementation had become more closely aligned with status 3 rather than status 2 (**Figure 1)**.[25]

Figure 1 Waitlist Mortality for Status 2 Candidates Qualifying by IABP Compared to Overall Adult Statuses 2 and 3



Note: Post-implementation era: October 18, 2018, through October 17, 2022.

The Committee compared the waitlist mortality rates of IABP to the status 3 rates, and to the non-IABP status 2 rates.[26] The Committee initially discussed moving the IABP criterion from status 2 to status 3 to

[19] Hanff et al., "Heart Waitlist Survival in Adults," 370.
[20] Hanff et al., "Heart Waitlist Survival in Adults," 370.
[21] Hanff et al., "Heart Waitlist Survival in Adults," 369.
[22] Amrut V. Ambardekar and Jordan R.H. Hoffman, "Newton's Laws of Heart Transplant Allocation," *The Journal of Heart and Lung Transplantation,* vol. 42,2 (2023): 207. doi:10.1016/j.healun.2022.11.001.
[23] William F. Parker et al., "Practice Changes at U.S. Transplant Centers After the New Adult Heart Allocation Policy," *Journal of The American College of Cardiology,* vol 75, 23 (2020): 2913. https://doi.org/10.1016/j.jacc.2020.01.066.
[24] Parker et al., "Practice Changes at U.S. Transplant Centers," 2912.
[25] "Three-Year Monitoring of Heart Allocation Proposal," p. 31.
[26] Meeting Summary for October 11, 2022, meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/u5qdbb3e/20221011_heart_meeting-summary_final.pdf..

properly align the waitlist mortality rates. Another potential solution that was discussed would require reporting of inotropic use and hemodynamic measurements of candidates with an IABP to justify the use of the device.[27] As the Committee began to take steps in building the framework for continuous distribution of hearts, the determination was made to address the unintended increase in IABP use by forming the IABP Status Subcommittee. The intent of the Subcommittee was to focus on developing a consensus solution, while the full committee remained focused on continuous distribution. The Subcommittee considered the two possible solutions.[28]

The Subcommittee quickly determined moving the IABP to status 3 was unfeasible. First, doing so could disadvantage candidates in which an IABP is the optimal therapy, demonstrated by meeting clinical criteria. The relative affordability of an IABP compared to other devices, and the relative medical ease of inserting the device, makes it a good option for many candidates whose cardiogenic shock cannot be stabilized by inotropes, or who are experiencing an emergency situation in which medical staff must act quickly to stabilize the candidate.[29]

The Subcommittee then considered the second option, which would require reporting initial attempts to administer inotropic therapy and demonstrate hemodynamics to justify the use of an IABP. If inotropes are administered, and the candidate's condition does not improve, the use of an IABP would be seen as a reasonable option to further assist the heart in pumping blood throughout the body. Also, this solution demonstrates the medical urgency of the candidate by providing more detail about attempts to wean the candidate off the device when applying for status 2 extensions. Finally, the inotropic therapies that are used prior to placing an IABP, and to wean a candidate off an IABP, are consistent with the requirements in status 3 *OPTN Policy 6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope Hemodynamic Monitoring*. By adopting the inotropic therapy criteria already used in heart policy, a transplant program can clearly demonstrate an escalation of urgency justifying the candidate being listed at status 2. For status 2 extensions, the same inotropic and similar hemodynamic information is required to demonstrate attempts to wean a candidate off the IABP were unsuccessful which justifies the continued listing of the candidate in status 2.[30]

The Subcommittee felt confident this solution achieved the goal of addressing the use of IABP by transplant programs on less urgent candidates to list the candidate in higher status. This solution, however, did not address Subcommittee member concerns regarding other devices being used in the same way. To prevent the same unintended consequence from occurring with another device, the Subcommittee determined the best solution would be requiring the same inotropic and hemodynamic information for both IABP in *OPTN Policy 6.1.B.v Intra-Aortic Balloon Pump (IABP)* and all percutaneous endovascular MCSDs in *OPTN Policy 6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device.*[31] The other devices listed within status 2, such as TAH and BiVAD, were determined by the Subcommittee to require surgical procedures far too invasive to result in the same unintended consequence to necessitate more strict criteria in their use.[32] Finally, the Subcommittee provided a path

[27] Meeting Summary for October 11, 2022, meeting, OPTN Heart Transplantation Committee.
[28] Meeting Summary for October 11, 2022, meeting, OPTN Heart Transplantation Committee.
[29] Meeting Summary for April 6, 2023, meeting, OPTN Heart Transplantation Committee, IABP Subcommittee, https://optn.transplant.hrsa.gov/media/laij1eqm/20230406_iabpsubco_meeting-summary.pdf.
[30] Meeting Summary for April 6, 2023, meeting, OPTN Heart Transplantation Committee, IABP Subcommittee, https://optn.transplant.hrsa.gov/media/laij1eqm/20230406_iabpsubco_meeting-summary.pdf.
[31] Meeting Summary for April 13, 2023, meeting, OPTN Heart Transplantation Committee, IABP Subcommittee, https://optn.transplant.hrsa.gov/media/oabhcllh/202230413_iabpsubco_meeting-summary.pdf.
[32] Meeting Summary for April 13, 2023, meeting, OPTN Heart Transplantation Committee, IABP Subcommittee, https://optn.transplant.hrsa.gov/mdia/oabhcllh/202230413_iabpsubco_meeting-summary.pdf..

for use of both percutaneous endovascular MCSDs and IABP in emergency situations by aligning criteria regarding these specific situations within policy that do not require inotropes or hemodynamics during the initial justification for listing in status 2.

To determine the impact and effectiveness of this proposed policy change, a data analysis was performed by the OPTN examining all adult heart candidates who qualified for adult status 2 by IABP between October 18, 2018, and October 17, 2021.[33] The question of what proportion of candidates would be impacted by this policy change was examined in two ways. The first analysis examined the proportion of candidates who had qualified for adult status 2 by IABP who also had previously qualified for adult status 3 based on a combination of inotropes and hemodynamic monitoring (**Figure 2**). Of the 2,206 total registrations submitted for status 2 with an IABP, 16.8 percent (370 registrants) had previously submitted a status 3 justification form that listed attempted inotropic therapy. The remaining 83.2 percent (1,836 registrants) did not list any attempted inotropic therapy and would not qualify under the new proposed requirements.

Figure 2 Qualifying Candidates Under Proposed Changes Based on Justification Form Data

The second analysis examined the risk stratification data of the registrations and the reported use of inotropes (**Figure 3**). Of the same 2,206 registrations only 34.7 percent (765 registrants) listed a single high dose, or multiple doses, of inotropes with hemodynamic measurements, the remaining 65.3 percent (1,441 registrants) did not list attempted inotropic therapy and would not qualify under the new proposed requirements.

Figure 3 Qualifying Candidates Under Proposed Changes Based on Risk Stratification

[33] OPTN Descriptive Data Request, "Changes to Status 2 IABP Requirements Data Request," Prepared for OPTN Heart Transplantation Committee, IABP Subcommittee Conference Call, May 04, 2023.

This suggests that between 65 percent and 83 percent of candidates qualifying for adult status 2 by IABP between October 18, 2018, and October 17, 2021, would not have qualified for status 2 with this policy change.

When presented with the Subcommittee's proposed policy changes, the full Committee ultimately agreed this was the most effective course of action. The Committee discussed whether the policy change would limit a transplant program's ability to list a candidate with an IABP in any status. It was noted that candidates on an IABP may still qualify for status 3 and status 6 criteria if the transplant program cannot demonstrate that the candidate would qualify for the proposed new inotropic and hemodynamic criteria in status 2.[34] The Committee supported adding the same criteria to status 2 percutaneous endovascular MCSDs, and left the emergency criteria that does not require hemodynamic measurements or the initial use of inotropes in place as it is in current policy.[35]

Overview of Proposal

The Committee proposes adding additional inotropic and hemodynamic requirements within seven days prior to the use of an IABP or percutaneous endovascular MCSD for candidates to be listed in status 2. Additionally, in the case of emergency interventions other measurements may be obtained. The proposed inotrope levels are identical to the status 3 criteria found in *OPTN Policy 6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring*. The Committee decided that these criteria demonstrate a clear need for both an IABP and percutaneous endovascular MCSD, and listing a candidate in status 2 rather than status 3. For extending a candidate at status 2, transplant programs will need to demonstrate the continued need of the device by reporting continued inotrope therapy and hemodynamic measurements. These hemodynamic measurements are currently in policy, adding ongoing inotrope therapy to the extension criteria will show the necessity of the device and the need for the candidate to remain at status 2.

Medicinal and Hemodynamic Reporting Changes

For the initial listing of a candidate at adult heart status 2, within seven-days prior to implanting an IABP or percutaneous endovascular MCSD support, the transplant program must document attempted inotropic therapy. Transplant programs have two options for appropriate inotropic therapy to satisfy the first criteria. The first option is at least one high-dose of the following intravenous inotropes:

- Dobutamine (greater than or equal to 7.5 mcg/kg/min)
- Milrinone (greater than or equal to 0.50 mcg/kg/min)
- Epinephrine (greater than or equal to 0.02 mcg/kg/min)

The second option is at least two 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)

[34] Meeting Summary for May 16, 2023, meeting, OPTN Heart Transplantation Committee. https://optn.transplant.hrsa.gov/media/tm1ivsf3/20230516_optn-heart-committee_meeting-summary_final.pdf.
[35] Meeting Summary for May 16, 2023, meeting, OPTN Heart Transplantation Committee.

The second criteria, within one 24-hour period of the same seven days prior to the implant of the device, all the following hemodynamic measurements must be true while receiving the inotropic therapy:

- Systolic blood pressure of less than 90 mmHg
- Cardiac index of less than 2.0 L/min/m^2
- Pulmonary capillary wedge pressure of greater than 15 mmHg

If the hemodynamic measurements could not be obtained within the seven-day period, a program can list a candidate for status 2 with an IABP or percutaneous endovascular MCSD if within a 24-hour period prior to the device being used any one of the following are true:

- CPR was performed on the candidate
- Systolic blood pressure was less than 70 mmHg
- Arterial lactate was greater than 4 mmol/L
- AST or ALT was greater than 1,00U/L

Meeting either of the criteria will allow a transplant program to list a candidate at status 2 with an IABP or percutaneous endovascular MCSD for 14 days. The transplant program will need to reapply for a status 2 extension every 14 days if the candidate remains on the device and the transplant program demonstrates a failure to wean the candidate off the device by submitting the following to the regional review board:

- The candidate is still supported by the same single high dose, or two lower doses, inotropes required for the initial listing
- The candidate demonstrated a contraindication to being supported by a durable device
- Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from the IABP or percutaneous endovascular MCSD evidenced by at least one of the following:
    - Mean arterial pressure (MAP) less than 60 mmHg
    - Cardiac index less than 2.0 L/min/m2
    - Pulmonary capillary wedge pressure greater than 15 mmHg
    - SvO2 less than 50 percent measured by central venous catheter

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."[36] The OPTN Final Rule states the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[37] This policy change addresses equitable allocation by ensuring similarly situated patients receive offers by modifying the criteria for qualifying for status 2 through use of an IABP to ensure a candidate's status accurately represents their waitlist mortalities.

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

[36] 42 U.S.C. § 274(b)(2)(B).
[37] 42 C.F.R. § 121.4(a)(1).

"(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."[38] This proposal:

- **Is based on sound medical judgement**[39] because it is an evidence-based change relying on the following evidence:
    - Data collected from OPTN Monitoring reports, data requests, and medical research journals.
    - Medical judgement that heart allocation is aligned based on waitlist mortality rates, does not disadvantage patients within the same status, and evidence that shows a misalignment of mortality rates within status 2 among patients with an IABP device.
- **Seeks to achieve the best use of donated organs**[40] by ensuring organs are allocated and transplanted according to medical urgency:
    - Status 2 candidates should all have similar waitlist mortalities and medical urgency, but evidence demonstrates that patients with an IABP currently have mortality rates that do not align with the status 2 classifications. Requiring the reporting of other medical therapies prior to the use of an IABP should allow for greater access to organ offers for patients with similar waitlist mortality rates.

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]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Is designed to avoid wasting organs[43]
- Is designed to avoid futile transplants[44]
- Is designed to…promote patient access to transplantation[45]
- Promotes the efficient management of organ placement[46]
- Is not based on the candidate's place of residence or place of listing[47]

[38] 42 C.F.R. § 121.8(a).
[39] 42 C.F.R. § 121.8(a)(1).
[40] 42 C.F.R. § 121.8(a)(2).
[41] 42 C.F.R. § 121.8(a)(3).
[42] 42 C.F.R. § 121.8(a)(4).
[43] 42 C.F.R. § 121.8(a)(5).
[44] Id.
[45] Id.
[46] Id.
[47] 42 C.F.R. § 121.8(a)(8).

Transition Plan

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[48] The Committee recognized there could be candidates who had qualified as status 2 under the current policy that would not qualify for that status under the policy change at the time of implementation. Those candidates will remain at status 2 until the expiration of the approved form. An extension of the approved form will not be available, a new initial form should be submitted by the transplant program for the candidate to maintain the status. If a new initial form is not submitted by the transplant program prior to expiration the candidate will be downgraded as outlined in policy. The Committee seeks community feedback regarding whether this is the most appropriate course of action, or whether there might be more efficient and effective options to ensure all candidates are assigned to the correct status following implementation.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Transplant hospitals will need to ensure their staff are made aware of the changes to status 2 IABP and percutaneous endovascular MCSD qualifying criteria. These changes may prompt changes to clinical practice. Staff will also need to be aware of data collection changes to the status 2 justification and extension forms.

Operations affecting the OPTN

The OPTN Contractor will need to update the status 2 IABP and percutaneous endovascular MCSD justification forms. The OPTN Contractor will need to make transplant programs aware of the policy changes and the changes to the status 2 justification and extension forms.

Potential Impact on Select Patient Populations

Some candidates listed in status 2 without an IABP may see an increase in organ offers. Additionally, some candidates on an IABP or percutaneous endovascular MCSD may be reassigned to a lower status if their transplant program does not submit the appropriate inotropic therapy information on their justification forms. Finally, there may be an initial surge of candidates within in status 3 or status 6 as candidates with an IABP are assigned to new statuses.

Projected Fiscal Impact

The proposal was determined to have a low overall fiscal impact on the OPTN, organ procurement organizations and transplant hospitals. No fiscal impact was recorded for histocompatibility labs.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact on Histocompatibility Laboratories.

[48] 42 C.F.R. § 121.8(d)(1).

Projected Impact on Organ Procurement Organizations

This proposal is not expected to have a significant impact on OPOs since OPO staff do not list candidates.

Projected Impact on Transplant Hospitals

This proposal may require a minor increase training for heart transplant staff, an increase in time entering additional data in charts and reviewing chart and data entries, and the possibility of additional internal compliance audits during the proposal's implementation. There will be no ongoing implementation costs or increase in long-term staff burden. Notably, depending on how many IABP patients are waitlisted at a transplant hospital, there could be an initial increase in status change submissions.

Projected Impact on the OPTN

The OPTN Contractor estimates 2800 hours for technical implementation. Implementation will involve updates to the initial adult heart status 2 form, and the adult heart status 2 extension form. The OPTN Contractor estimates 80 hours for ongoing support. Ongoing support includes contractor staff processing status 2 exception requests, post-implementation monitoring, and education of members of the policy change.

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." This proposal will not change the current routine monitoring of OPTN members. Any data entered into OPTN computer systems may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

This policy will be formally evaluated at six, twelve, and eighteen months post-implementation. All metrics will be evaluated as data become available, with appropriate lags applied per typical OPTN conventions to account for the time delay in institutions reporting data and compared to an appropriate pre-policy cohort. The reporting timeline is subject to change based on the results.

The following metrics, and any additional metrics requested by the Committee, will be evaluated:

- The total number of candidates qualifying for adult status 2, overall and for candidates qualifying by IABP and percutaneous endovascular MCSD specifically
- Waiting list mortality for adult status 2 candidates, overall and for candidates qualifying by IABP and percutaneous endovascular MCSD specifically

Conclusion

This policy seeks to address the increasing usage of IABP in status 2 candidates and seeks to improve the stratification of candidates on the heart waiting list. This proposal offers a fair and reasonable solution, based on medical best practices that do not disadvantage candidates who meet commonly accepted medical requirements for an IABP. Additionally, this proposal seeks to prevent further congestion within status 2 by applying the same standard to percutaneous endovascular MCSDs.

Considerations for the Community

- Does this proposal sufficiently address the issue of IABP usage within status 2? Describe why or why not.
- Is adult heart status 3 more appropriate for the IABP criterion currently in status 2? Is this also true for percutaneous endovascular MCSDs criterion in status 2?
- Are the prerequisite parameters for IABP and percutaneous endovascular MCSDs appropriate given the specific need of some candidates?
- Should the proposed policy changes to adult heart status 2 IABP and percutaneous endovascular MCSD criteria also define the amount of time a candidate must receive a continuous infusion of the inotropic therapy before the candidate would qualify for the status assignment?
- Are the inotropic levels that are listed within the policy appropriate for use prior to the placement of an IABP? If not, what levels would be more appropriate and why?
- Should the duration of the initial assignment, and/or the extension, be reduced from 14 days? If yes, please describe why and what might be a more appropriate time period.
- Do members of the patient community feel this action is appropriate to give greater access to more medically urgent candidates?
- Under the proposed transition plan, following implementation, a candidate would remain at the assigned status until the expiration of the justification form, at which point the transplant program would need to submit a new justification form. Is that the most appropriate way to address such adult heart status 2 candidates following implementation? Are there more efficient and effective options to ensure all candidates are assigned to the correct status following implementation?

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.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by a percutaneous endovascular mechanical circulatory support device without an oxygenator for cardiogenic shock, as evidenced by *either* of the following:

- Within 7 days prior to percutaneous endovascular mechanical circulatory support, *both* of the following are true:
  1. The candidate's cardiogenic shock was not stabilized after receiving qualifying inotropic therapy, considered as either of the following:
     - A continuous infusion of at least one high-dose intravenous inotrope:
       - Dobutamine greater than or equal to 7.5 mcg/kg/min
       - Milrinone greater than or equal to 0.50 mcg/kg/min
       - Epinephrine greater than or equal to 0.02 mcg/kg/min
     - A continuous infusion of at least two intravenous inotropes:
       - 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
  2. ~~*All* of the following are true~~ ~~w~~While receiving qualifying inotropic therapy, *all* of the following measurements are obtained for the candidate within one 24-hour period:
     a. Systolic blood pressure of less than 90 mmHg
     b. Cardiac index ~~less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or~~ of less than 2.0 L/min/m^2 ~~if the candidate is supported by inotropes~~
     c. Pulmonary capillary wedge pressure of greater than 15 mmHg

- If hemodynamic measurements could not be obtained within 7 days prior to percutaneous endovascular mechanical circulatory support, at least *one* of the following is true within 24 hours prior to percutaneous endovascular mechanical circulatory support:
    - CPR was performed on the candidate
    - Systolic blood pressure less than 70 mmHg
    - Arterial lactate greater than 4 mmol/L
    - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the percutaneous endovascular mechanical circulatory support device. The transplant program must provide to the RRB objective evidence of *all* ~~*both*~~ of the following:

1. The candidate is supported by qualifying inotropic therapy
2. The candidate demonstrated a contraindication to being supported by a durable device
3. Within 48 hours prior to the status expiring, the transplant program demonstrated a failure to ~~failed at~~ wean~~ing~~ the candidate from the percutaneous endovascular mechanical circulatory support device evidenced by at least *one* of the following:
    - Mean arterial pressure (MAP) less than 60 mmHg
    - Cardiac index less than 2.0 L/min/m^2
    - Pulmonary capillary wedge pressure greater than 15 mmHg
    - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the percutaneous endovascular mechanical circulatory support device after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.v Intra-Aortic Balloon Pump (IABP)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by an IABP for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to IABP support, both of the following are true:
    1. The candidate's cardiogenic shock was not stabilized after receiving either of the following:
        - A continuous infusion of at least one high-dose intravenous inotrope:
            - Dobutamine greater than or equal to 7.5 mcg/kg/min
            - Milrinone greater than or equal to 0.50 mcg/kg/min

- Epinephrine greater than or equal to 0.02 mcg/kg/min
- A continuous infusion of at least two intravenous inotropes:
  - 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

2. ~~*All* of the following are true w~~While receiving qualifying inotropic therapy, *all* of the following measurements are obtained for the candidate within one 24-hour period:
   a. Systolic blood pressure of less than 90 mmHg
   b. Cardiac index ~~less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or~~ of less than 2.0 L/min/m^2 ~~if the candidate is supported by inotropes~~
   c. Pulmonary capillary wedge pressure of greater than 15 mmHg

- If hemodynamic measurements could not be obtained within 7 days prior to IABP support, at least *one* of the following is true within 24 hours prior to IABP support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - AST or ALT greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the IABP. The transplant program must provide to the RRB objective evidence of *all* of the following:

1. The candidate is supported by qualifying inotropic therapy
2. The candidate demonstrated a contraindication to being supported by a durable device
3. Within 48 hours prior to the status expiring, the transplant program demonstrated a failure to ~~failed at~~ wean~~ing~~ the candidate from the IABP as evidenced by at least *one* of the following:
   - Mean arterial pressure (MAP) less than 60 mmHg
   - Cardiac index less than 2.0 L/min/m2
   - Pulmonary capillary wedge pressure greater than 15 mmHg
   - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the IABP after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

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