OPTN

Public Comment Proposal

Escalation of Status for Time on Left Ventricular Assist Device

OPTN Heart Transplantation Committee

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Escalation of Status for Time on Left Ventricular Assist Device

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Sponsoring Committee:	*Heart Transplantation*
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Executive Summary

Among the objectives of the heart allocation policy changes implemented in October 2018 was better stratification of the most medically urgent heart transplant candidates.[1] The changes were also intended to reflect the increased use of mechanical circulatory support devices (MCSD) and increased prevalence of MCSD complications.[2] While it appears the changes have largely achieved the intended goals, they may have unintentionally over-incentivized transplant programs into using temporary mechanical support devices ahead of dischargeable left ventricular assist devices (LVAD), even if the LVAD might have been more appropriate for the candidate.[3,4]

The OPTN Heart Transplantation Committee (Committee) is seeking to incentivize transplant programs' use of dischargeable LVADs more frequently given the benefits associated with the devices, such as the improved waitlist mortality rates documented in the literature.[5,6,7] The Committee proposes allowing dischargeable LVAD candidates to transition to a higher priority status based on an established number of years after device implantation. Providing candidates who have been supported by their LVAD for an extended period of time with access to a higher status will increase their likelihood of being transplanted before experiencing a device complication or death while waiting. The Committee's proposed changes would be implemented in two phases. In Phase 1, dischargeable LVAD candidates will qualify for status 2 when their device has been implanted for at least eight years and for status 3 when their device has been implanted for at least six years. The changes will be in effect for 18 months, at which time the implementation of Phase 2 will occur. Under Phase 2, such candidates will qualify for status 2 and 3 after at least seven and five years of device implantation, respectively. The phased

[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 July 9, 2024).
[2] Ibid.
[3] Keighly Bradbrook et al., "A National Assessment of One-Year Heart Outcomes After the 2018 Adult Heart Allocation Changes," *The Journal of Heart and Lung Transplantation* 42, no. 2 (2023): 196-205. https://doi.org/10.1016/j.healun.2022.08.018.
[4] Les James and Deane E. Smith, "Bridging Over Troubled Waters-How the United States 2018 Heart Allocation System Altered Transplant Bridging Strategies," *Reviews in Cardiovascular Medicine* 25, no. 2 (2024): 68-. https://doi.org/10.31083/j.rcm2502068.
[5] Maya Barghash et al., "Durable LVADs as a Bridge to Transplantation," *JACC. Heart Failure* 11, no. 9 Pt 2 (2023): 1160-63. https://doi.org/10.1016/j.jchf.2023.07.011.
[6] Ulrich P. Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report: Focus on Magnetically Levitated Devices," *The Annals of Thoracic Surgery* 117, no. 1 (2024): 33–44. https://doi.org/10.1016/j.athoracsur.2023.11.004.
[7] Anubodh S. Varshney and Jeffrey J. Teuteberg, "Durable Mechanical Circulatory Support: The Spring of Hope or the Winter of Despair?," *Journal of Cardiac Failure* 30, no. 8 (2024): 1041–43. https://doi.org/10.1016/j.cardfail.2024.03.015.

approach provides time to analyze the policy changes' effectiveness before further expanding the population of eligible candidates.

Purpose

The proposal provides a meaningful pathway for adult heart candidates who have been supported by dischargeable LVADs for a determined number of years since device implant to receive increased priority because of the increasing risk of experiencing an adverse event leading to reduced survival.[8,9] To fully accomplish their objective, the Committee proposes using a "step-down" approach regarding the eligibility timeframes, which will be implemented in two phases. In Phase 1, the Committee is proposing that an adult candidate who has had a dischargeable LVAD implanted for at least six years will be eligible for assignment at status 3. Additionally, if a candidate has had a dischargeable LVAD implanted for at least eight years then the candidate will be eligible for assignment at adult status 2.

The Committee is also proposing that 18 months after implementation of the aforementioned policy changes, Phase 2 of the proposal would be effective, and the eligibility timeframes will "step-down" to five and seven years, respectively. Phasing in the time requirement avoids adversely impacting existing status 3 and 2 patients by absorbing the new qualifiers more gradually.

The Committee believes the step-down approach reflects sound medical judgment based partly on research findings indicating that dischargeable LVAD candidates experience longer-term patient morbidity and mortality the longer they are supported by the device.[10] Therefore, even though stable LVAD candidates are assigned to adult heart status 4, the risk of experiencing a device complication or malfunction is greater for groups of candidates based on the amount of time they have been supported by their devices.

Background

Allocation Changes Implemented in October 2018 Resulted in Fewer Waitlist Registrations and Transplants of Dischargeable LVAD Patients

The policy modifications implemented in October 2018 created six adult heart statuses where previously there had been three. As described in the Briefing Paper, the additional statuses were intended to create more granular statuses based on waitlist mortality and other clinical factors "in order to ensure that candidates in most need have access to donor hearts first."[11] Following implementation of the allocation policy changes, the heart community has had growing concerns that dischargeable LVADs are no longer considered a viable bridge-to-transplantation option. Specifically, the community is concerned that there has been a shift away from providing dischargeable LVADs as a bridge-to-transplant towards the use of temporary support such as intra-aortic balloon pumps (IABP), temporary LVADs, or even Extracorporeal Membrane Oxygenation (ECMO).[12] Critics of the changes point out that fewer candidates

[8] Note: Dischargeable LVAD refers to a LVAD that is approved by the U.S. Food and Drug Administration for use outside of a hospital setting.

[9] Imad Hariri et al., "Long-Term Survival on LVAD Support: Device Complications and End-Organ Dysfunction Limit Long-Term Success," The Journal of Heart and Lung Transplantation 41, no. 2 (2022): 161-70. https://doi.org/10.1016/j.healun.2021.07.011

[10] Hariri et al., "Long-Term Survival on LVAD Support," pp. 162, 165.

[11] *Proposal to Modify the Adult Heart Allocation System*, December 2016.

[12] Bradbrook et al., "A National Assessment of One-Year Heart Outcomes."

who are supported by dischargeable LVADs are being transplanted while assignments to adult heart status 2 by use of IABP have increased.[13,14,15,16]

According to Ambardekar and Hoffman, because the 2018 changes defined disease severity based on the heart therapy provided, transplant programs were essentially encouraged to use therapies associated with higher priority statuses when therapies associated with lower priority statuses may have been equally effective.[17] For example, Varshney, et. al. reported that "in the year after implementation of the new [OPTN] donor heart allocation system, temporary MCS use in patients admitted with ADHF-CS [acute, decompensated, heart failure-related cardiogenic shock] increased in US transplant centers, not in other CICUs [cardiac intensive care units]" suggesting that "changes in practitioners' management strategies for patients" with cardiogenic shock may have been driven by the changes in OPTN allocation policy rather than improved outcomes for such patients when compared to other forms of therapy.[18]

OPTN Heart Committee Efforts to Address Concerns

In 2023, the Committee proposed and the OPTN Board of Directors (Board) approved policy changes addressing the high volume of assignments to adult heart status 2 based on the use of intra-aortic balloon pumps (IABP).[19] The eligibility requirements associated with the intra-aortic balloon pump (IABP) criterion were considered to be less reflective of the waitlist mortality rates associated with the other adult status 2 criteria.[20] The changes to the status 2 IABP and the status 2 percutaneous endovascular mechanical circulatory support device (MCSD) criteria require transplant programs to demonstrate a failure of inotropic therapy to stabilize the candidates' cardiogenic shock before proceeding to placement of an IABP or percutaneous endovascular MCSD. The changes the Board approved are expected to help status 3 and status 4 candidates, including those supported by dischargeable LVADs, receive more allocation offers.[21]

However, the Board-approved changes had yet to be implemented as of December 2024. Moreover, by themselves the policy changes are not expected to sufficiently alleviate the concerns held for dischargeable LVAD candidates who have waited a substantial amount of time after their device was implanted. Additionally, the continuous distribution of hearts allocation system the Committee is currently developing is still several years from implementation.[22] The LVAD-specific changes the

[13] Meeting Summary for October 17, 2019 meeting, OPTN Thoracic Transplantation Committee, https://optn.transplant.hrsa.gov/media/3330/20191017_thoracic-committee_minutes.pdf (Accessed June 26, 2024).
[14] Bradbrook et al., "A National Assessment of One-Year Heart Outcomes."
[15] Barghash et al., "Durable LVADs as a Bridge to Transplantation."
[16] A*mend Adult Heart Status 2 Mechanical Device Requirements*, OPTN Heart Transplantation Committee, December 2023, https://optn.transplant.hrsa.gov/media/vq4pgeb1/heart_amend-adult-heart-status-2_bp_dec23.pdf (Accessed December 10, 2024).
[17] Amrut V. Ambardekar and Jordan R.H. Hoffman, "Newton's Laws of Heart Transplant Allocation," *The Journal of Heart and Lung Transplantation* 42, no. 2 (2023): 206-8. https://doi.org/10.1016/j.healun.2022.11.001.
[18] Anubodh S. Varshney et al., "Use of Temporary Mechanical Circulatory Support for Management of Cardiogenic Shock Before and After the United Network for Organ Sharing Donor Heart Allocation System Changes," *JAMA Cardiology* 5, no. 6 (2020): 703–8. https://doi.org/10.1001/jamacardio.2020.0692.
[19] *Notice of OPTN Policy and Data Collection Changes: Amend Adult Heart Status 2 Mechanical Device Requirements*, OPTN Heart Transplantation Committee, Board approved December 4, 2023.
[20] A*mend Adult Heart Status 2 Mechanical Device Requirements*, OPTN Heart Transplantation Committee, December 2023, https://optn.transplant.hrsa.gov/media/vq4pgeb1/heart_amend-adult-heart-status-2_bp_dec23.pdf (Accessed December 10, 2024), pp. 5-6.
[21] Meeting Summary for May 4, 2023 meeting, OPTN Heart_IABP Status Subcommittee, https://optn.transplant.hrsa.gov/media/y1oh4u4n/20230504_iabpsubco_meeting-summary.pdf (Accessed November 23, 2024).
[22] Federal Register, https://www.federalregister.gov/documents/2024/11/01/2024-25506/agency-information-collection-activities-proposed-collection-public-comment-request-information#print (Accessed November 20, 2024).

Committee is proposing now would further increase the chances of receiving an organ offer for LVAD supported candidates.

Current Generation of Dischargeable LVADs Can Provide Years of Stable Support, But Is Still Viewed as a 'Bridge-to-Nowhere'

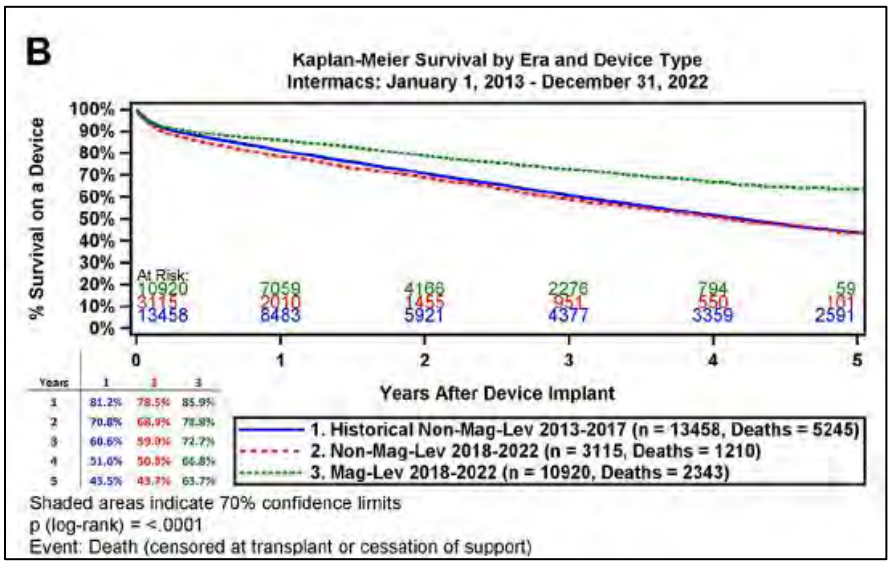
Based on randomized clinical trial data demonstrating their benefits over other devices, fully magnetically levitated (Mag-Lev) LVADs became the primary continuous flow LVAD being implanted beginning in 2018 and 2019.[23,24] The Mag-Lev LVADs are considered safer than previous generations of LVADs and evidence suggests that many patients can be supported for years uneventfully prior to transplant.[25,26] As a result, the devices can potentially serve as a meaningful extension of both quantity and quality of life for well-chosen candidates. Studies of LVADs suggest that currently the average event-free survival using a modern device appears to be about four to six years.[27,28]

LVADs carry a good and improving prognosis when utilized to support the appropriate type of candidate. For example, a 2022 analysis suggested that outcomes for all types of dischargeable LVADs are equivalent to heart transplant at two years.[29] An analysis published in 2024 found that patients supported by the HeartMate 3 LVAD device, a Mag-Lev device and the only dischargeable LVAD currently on the market in the United States, may have comparable 3-year survival to orthotopic transplantation as a primary treatment for heart failure.[30] Writing in the Society of Thoracic Surgeons Intermacs 2023 Annual Report, Jorde, et al., reported that 1- and 5-year survival rates improved for patients who had a dischargeable, continuous flow LVAD implanted during 2013 through 2022.[31]

Figure 1 is taken from the Intermacs 2023 Annual Report. The figure indicates that candidates supported by Mag-Lev devices had five year survival of approximately 64% (represented by dotted green line and reflected in the table).[32] The figure also indicates that candidates supported by Mag-Lev LVADs had better survival at 1- and 5-year survival than candidates supported by non-Mag-Lev devices.[33]

[23] Mandeep R. Mehra et al., "A Fully Magnetically Levitated Left Ventricular Assist Device — Final Report," *The New England Journal of Medicine* 380, no. 17 (2019): 1618–27. https://doi.org/10.1056/NEJMoa1900486.
[24] Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report."
[25] Mehra et al., "A Fully Magnetically Levitated Left Ventricular Assist Device."
[26] Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report."
[27] Ibid.
[28] Jacob Agronin et al., "Three-Year Left Ventricular Assist Device Outcomes and Strategy After Heart Transplant Allocation Score Change," *The American Journal of Cardiology* 226 (2024): 1–8. https://doi.org/10.1016/j.amjcard.2024.07.001.
[29] Anubodh S. Varshney et al., "Trends and Outcomes of Left Ventricular Assist Device Therapy," *Journal of the American College of Cardiology* 79, no. 11 (2022): 1092–1107. https://doi.org/10.1016/j.jacc.2022.01.017.
[30] Michael Kirschner et al., "Comparing 3-Year Survival and Readmissions between HeartMate 3 and Heart Transplant as Primary Treatment for Advanced Heart Failure," *The Journal of Thoracic and Cardiovascular Surgery*, 2024. https://doi.org/10.1016/j.jtcvs.2023.12.019 (Accessed November 21, 2024).
[31] Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report."
[32] Ibid.
[33] Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report," p. 39.

Figure 1: Continuous Flow-LVAD Survival Rates After 1- and 5-Years[34]



Despite such positive survival trends, the current environment disincentivizes the use of durable LVADs because they are no longer viewed as providing a bridge-to-transplant. According to Barghash et al., "[t]he new allocation system as designed has succeeded in increasing transplant rates for the most medically urgent patients, but it has come at the expense of reduced access to organs for stable" LVAD patients.[35] The authors report that post-implementation "patients receiving [LVAD] implants as a bridge to either transplant or to candidacy saw the progression to transplant get cut in half, from 35% to 18.6%."[36] Moreover, the authors state that "after 14 months, very few [dischargeable LVAD] patients were likely to receive a transplant."[37]

The term 'bridge-to-nowhere' has become associated with the devices because of the perception that the only way for a LVAD candidate to realistically get a transplant is to experience an adverse event that will escalate the patient to status 3 or higher, such as becoming hospitalized due to progression of their disease, bleeding or thromboembolic complication with the device, or device malfunction.[38,39,40,41,42]

As a Committee member pointed out, such findings may lead candidates and transplant programs to view LVADs as a 'bridge-to-nowhere.' As a result, there is little interest on the part of patients and programs to consider LVADs for support. Nonetheless, the Committee member continued, a transplant

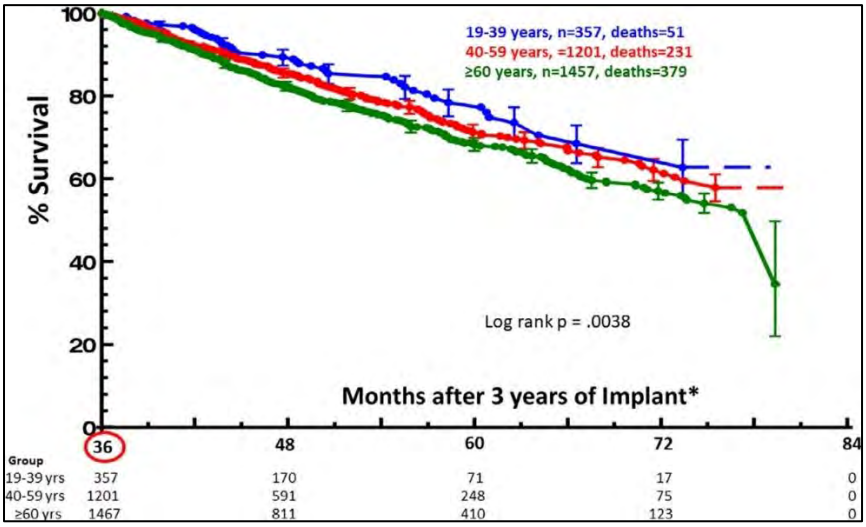
[34] Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report."
[35] Barghash et al., "Durable LVADs as a Bridge to Transplantation," p. 1161.
[36] Ibid.
[37] Ibid.
[38] Nicholas Hess et al., "Left Ventricular Assist Device Bridging to Heart Transplantation: Comparison of Temporary versus Durable Support," *The Journal of Heart and Lung Transplantation* 42, no. 1 (2023): 76–86. https://doi.org/10.1016/j.healun.2022.08.020.
[39] Kevin Chung and William F. Parker, "A Bridge to Nowhere: The Durable Left Ventricular Assist Device Dilemma in the New Heart Allocation System," *The Journal of Heart and Lung Transplantation* 42, no. 1 (2023): 87–88. https://doi.org/10.1016/j.healun.2022.10.012.
[40] Barghash et al., "Durable LVADs as a Bridge to Transplantation."
[41] Clancy W. Mullan et al., "Changes in Use of Left Ventricular Assist Devices as Bridge to Transplantation With New Heart Allocation Policy," *JACC. Heart Failure* 9, no. 6 (2021): 420–29. https://doi.org/10.1016/j.jchf.2021.01.010.
[42] David A. Baran et al. "Everything I Wanted," *JACC. Heart Failure* 9, no. 11 (2021): 858–59. https://doi.org/10.1016/j.jchf.2021.04.017.

program should not hospitalize a patient and surgically implant a percutaneous device in order to assign the patient to status 2 when the same patient could be waiting at home with a dischargeable LVAD.[43]

Many consider device complications to represent life-threatening events. A candidate's mortality and morbidity will increase the longer they spend supported by the device.[44,45] The risk of stroke, infection, and bleeding, as well as device malfunction, become greater the longer the device remains implanted. For example, Hariri and others reported findings that patients supported by dischargeable continuous flow LVADs who develop adverse events, such as mucocutaneous bleeding, right heart failure, and infection, experience reductions in longer term survival if the adverse event occurs within one year, within three years, or the events are recurrent.[46] According to their analysis, Hariri et al, found that "[e]ach episode of infection was associated with a 10% to 13% increase in the adjusted continuous hazard for long-term mortality after 1 and 3 years of" LVAD support.[47] As a result, the Committee seeks to allow candidates to transition to higher statuses before complications occur.

Figure 2 illustrates the ongoing risk of continued LVAD support in the long-term for patients who have done well initially. The figure depicts the results of an analysis performed by Hariri, et al., which found that for a group of patients in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) from 2012 to 2018, even those with a successful, dischargeable LVAD who were alive three years after implant had an on-going significant risk of death regardless of age group.[48] According to the analysis, the average survival was only 60% to 70% during the three years following three-year survival.[49]

Figure 2: Continued Risk in LVAD Candidates Alive Three Years After Device Implant[50]



[43] Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/pm5jfqkq/20240612_heart_committee-meeting-summary.pdf (Accessed November 24, 2024).
[44] James K. Kirklin et al., "Eighth Annual INTERMACS Report: Special Focus on Framing the Impact of Adverse Events," *The Journal of Heart and Lung Transplantation* 36, no. 10 (2017): 1080–86. https://doi.org/10.1016/j.healun.2017.07.005.
[45] Hariri et al., "Long-Term Survival on LVAD Support."
[46] Ibid.
[47] Ibid.
[48] Ibid.
[49] Ibid.
[50] Ibid.

The information in **Table 1** identifies deaths per 100 active patient years waiting by criteria within medical urgency status following the implementation of the allocation changes in October 2018.[51]

Table 1: Deaths Per 100 Active Patient Years Waiting by Criteria Within Medical Urgency Status Post-Implementation[52]

Adult Status	Criterion	Patients Ever Waiting	Number of Deaths	Deaths Per 100 Years	Confidence Interval
3	Dischargeable LVAD for discretionary 30 days	2,508	1	1	[0, 3]
3	Status 3 exceptions	2,030	9	5	[2, 10]
3	IABP after 14 days	77	0	0	--
3	MCSD with aortic insufficiency	121	0	0	--
3	MCSD with device infection	849	5	2	[1, 4]
3	MCSD with hemolysis	57	1	18	[0, 98]
3	MCSD with mucosal bleeding	84	0	0	--
3	MCSD with pump thrombosis	140	3	4	[1, 12]
3	MCSD with right heart failure	60	3	17	[4, 50]
3	Multiple/single high dose inotrope and hemodynamic monitoring	1,473	4	7	[2, 18]
3	Non-dischargeable, surgically implanted, non-endovascular LVAD > 14 days	3	0	0	--
3	Percutaneous endovascular circulatory support device after 14 days	21	0	0	--
3	VA ECMO after 7 days	4	0	0	--
4	Amyloidosis / hypertrophic / restrictive cardiomyopathy	932	8	2	[1, 4]
4	Congenital heart disease	691	9	2	[1, 4]
4	Dischargeable LVAD without discretionary 30 days	4,994	80	2	[1, 2]
4	Status 4 exceptions	1,776	17	3	[2, 5]
4	Inotropes without hemodynamic monitoring	2,213	12	3	[2, 6]
4	Ischemic heart disease with intractable angina	233	4	3	[1, 8]
4	Retransplant	482	19	7	[4, 10]

Under current heart allocation policy, an adult candidate supported by a dischargeable LVAD is likely to be assigned to status 4. Policy also permits transplant programs to assign adult candidates to status 3 for 30 days at their discretion. The objective behind the discretionary 30 days is to "provide candidates with a priority for a limited time without forcing them to risk developing a device complication in order to move up in urgency."[53] In essence, candidates supported by dischargeable LVADs and assigned to adult status 3 or 4 are essentially the same, and therefore, are useful for comparison purposes. Status 4 candidates with a dischargeable LVAD without discretionary 30 days had two deaths per 100 patient years.[54] Some status 3 LVAD candidates who develop a complication with their device experience

[51] OPTN Heart Transplantation Committee, "Five-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," March 29, 2024, Table 7: Deaths per 100 Active Patient-Years Waiting by Criteria within Medical Urgency Status Post Implementation, p. 35.
[52] Ibid.
[53] *Proposal to Modify the Adult Heart Allocation System (Public Comment Proposal)*, OPTN Thoracic Organ Transplantation Committee, August 15 – October 15, 2016, https://optn.transplant.hrsa.gov/media/1921/thoracic_adult_heart_allocation_modification_20160815.pdf, pp.13-14 (Accessed November 22, 2024). *Proposal to Modify the Adult Heart Allocation System (Public Comment Proposal)*, OPTN Thoracic Organ Transplantation Committee, January 25 – March 25, 2016, https://optn.transplant.hrsa.gov/media/1244/08_adult_heart_allocation_part1.pdf, pp. 15-16 (Accessed November 22, 2024).
[54] OPTN Heart Transplantation Committee, "Five-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System."

greater deaths per 100 patient years.[55] For example, MCSD with pump thrombosis candidates experienced four deaths per 100 active patient years, while candidates assigned to the status 3 criteria, MCSD with right heart failure or MCSD with hemolysis, experienced 17 and 18 deaths per 100 active patient years, respectively.[56]

Committee Seeks to Re-Emphasize Benefits of Dischargeable LVAD Support as a Therapy Option

With this proposal, the Committee aims to enable those with dischargeable LVADs to achieve a safe transplant, remove the disincentive to the use of such LVADs, and potentially reduce the number of patients brought to transplant in cardiogenic shock and hospitalized for months at a time at statuses 2 and 3. The Committee members also indicated their belief that the proposed changes will result in transplant programs submitting fewer requests to extend candidates' assignments at the high priority statuses 2 and 3, in favor of supporting such candidates through the use of dischargeable LVADs.[57]

The Committee first began considering how to increase prioritization for patients supported by LVADs when developing the *Amend Adult Heart Status 2 Mechanical Device Requirements* in 2023.[58] To account for LVAD recipients getting sicker or developing complications the longer they are supported by the device, the Committee created the IABP Status Subcommittee and tasked it with developing the intra-aortic balloon pump-related changes initially considered modifying policy to reflect the following:

- A candidate would be eligible for status 4 for the first year supported by LVAD
- For their second year of support, a candidate would be eligible for status 3, and
- For their third year and beyond, a candidate would be eligible for status 2.[59]

During the Committee's June 12, 2024 meeting, the members reviewed deaths per 100 active patient years waiting from the five-year monitoring report associated with the *Proposal to Modify the Adult Heart Allocation System*. In particular, they considered the deaths per 100 patient years for the following criteria:

- Status 3, dischargeable LVAD for discretionary 30 days, and
- Status 4, dischargeable LVAD without discretionary 30 days

The number of deaths per 100-patient years was very low for both criteria, as previously shown in **Table 1** (see page 8). The Committee considered the similarly low death rates and determined that because a pathway to status 3 already exists for stable LVAD candidates—even if for a short time—then it is appropriate to provide greater priority to similarly stable status 4 candidates to be assigned to status 3 due to their potential for experiencing an adverse event.

In addition, the Committee reviewed the median days to transplant for both criteria. According to the results of the analysis, the median days to transplant for the status 3, LVAD group was 47 days, or approximately one-and-a-half months. For the status 4 LVAD group, median days to transplant were 481 days, or about 16 months waiting. In light of the differences, the Committee was interested in identifying ways to discourage transplant programs from extending high medical urgency assignments, such as status 2 and 3, and to instead move forward with supporting their candidates using LVADs.

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[55] Ibid.
[56] Ibid.
[57] Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee.
[58] *Amend Adult Heart Status 2 Mechanical Device Requirements*.
[59] Meeting Summary for May 4, 2023 meeting, OPTN Heart_IABP Status Subcommittee, https://optn.transplant.hrsa.gov/media/y1oh4u4n/20230504_iabpsubco_meeting-summary.pdf (Accessed November 21, 2024).

The Committee members reviewed the survival rates depicted previously in **Figure 1** (see page 6) when discussing how many years after device implant a candidate must wait before being eligible to transition to status 2 or status 3.[60] The members agreed that providing eligibility to a higher status for candidates supported by a LVAD who have been waiting a long time, requires that the time waiting match the level of urgency associated with the statuses.[61] The Committee tried to balance the length of time since implant against the length of time that would incentivize transplant programs to stop extending the current status 2 and 3 candidates, and instead move forward by implanting more LVADs.[62]

Committee's Efforts Prioritizing Stable LVAD Candidates Was Challenging

From the outset of their discussions, the Committee agreed that the mortality and morbidity data should guide their decision-making while also acknowledging that the data presents challenges to their effort. The appropriate amount of priority to provide stable, dischargeable LVAD candidates has been an on-going discussion within the heart community. [63,64] The candidates who will benefit from the proposed policy changes are likely to be considered relatively well enough to have been waiting for a long time at home without complication. Conversely, candidates currently assigned to adult status 2 or status 3 are likely to be hospitalized, unwell, and experiencing complications associated with their LVAD.

The Committee had multiple discussions about the appropriateness of providing such high priority to individuals whose waitlist mortality rates are likely to be much better than other groups of patients assigned to statuses 2 and 3.[65,] For example, members questioned the appropriateness of assigning the same medical urgency to a stable, at-home LVAD patient as a status 2 candidate who is admitted to the hospital.[66] Some members asked whether there is enough evidence supporting the claim that status 4 patients with dischargeable LVADs are disadvantaged under the current allocation framework.[67]

Several journal articles cited in this proposal describe the patient acuity associated with developing a device complication, but until an adverse event occurs a stable LVAD candidate is likely an outpatient with a relatively good quality of life. As a result, determining priority often involves trying to account for the likelihood of developing a complication or experiencing a malfunction the longer a candidate waits with an implanted device.

Limitations of the current allocation system's reliance on support devices also make it difficult to assess waitlist mortality accurately. For example, a candidate experiencing temporary cardiogenic shock may be treated with an intra-aortic balloon pump (IABP) or a percutaneous endovascular mechanical circulatory support device (MCSD), where the purpose of each device is to treat the shock and stabilize

[60] Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee.
[61] Ibid.
[62] Ibid.
[63] Varshney and Teuteberg, "Durable Mechanical Circulatory Support," p. 1042.
[64] Barghash et al., "Durable LVADs as a Bridge to Transplantation," p. 1162.
[65] Meeting Summary for October 9, 2024 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/wwubkkbg/20241009_heart_committee-meeting-summary-final.pdf (Accessed November 17, 2024). Meeting Summary for November 6, 2024 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/rgxnlvpn/20241106_heart_committee-meeting-summary.pdf (Accessed December 12, 2024). Meeting Summary for July 2, 2024 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/iy5hgldt/20240702_heart_committee-meeting-summary.pdf (Accessed November 17, 2024).
[66] Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee.
[67] Ibid.

the patient. As a result, the severity of the candidate's illness may be, to some degree, masked by the support device.[68]

Committee Has Previously Wrestled With Prioritizing Stable LVAD Candidates

This is not the first time determining how much priority to assign dischargeable LVAD candidates has been difficult. A similar debate about how much priority stable LVAD candidates should be assigned occurred in 2015 and 2016 during the development of the current heart allocation framework and is also relevant to this proposal. Under the previous allocation policy framework, stable adult LVAD candidates were eligible for assignment at the highest priority status for up to 30 days based on the transplant program's discretion. When developing the allocation changes in 2015 and 2016, the Committee had extensive discussions as to whether the 30-day discretionary time should be maintained.[69,70] The Committee proposed keeping the criterion but giving it less priority by including it as part of a new status 3 category being proposed. There were also discussions about eliminating it. The Committee and the public were split over the extent to which the medical urgency of stable LVAD candidates was similar to that of other candidates who would also be assigned to the status 3 category.[71] Ultimately, the Committee determined that it was an acceptable compromise to maintain the 30-day discretionary criterion as part of adult heart status 3.[72,73] As noted in the 2016 briefing paper, the criterion "provides candidates supported by an LVAD with an opportunity for transplant while stable, which likely increases the opportunity for successful transplantation prior to the development of a device-related complication."[74]

Proposed Policy Changes Reflect Committee's Prioritization Efforts and Commitment Not to Adversely Impact Waitlist Mortality of Existing Status 2 and 3 Candidates

The Committee members strongly agreed that it would be unacceptable to reduce the waitlist mortality of the candidates already assigned to statuses 2 and 3 in order to provide grafts to patients with uneventful LVAD support. With that objective in mind, they considered how the proposed policy changes might result in increased waitlist additions and the potential impact the increase would have on candidates already assigned to adult status 2 and 3. The members quickly realized there could be a rapid increase in candidates assigned to status 2 and status 3 when the proposed changes are implemented.

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[68] Meeting Summary for March 29, 2024 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/pfpcrzc4/20240329_heart_committee-meeting-summary.pdf (Accessed November 25, 2024).

[69] The OPTN Heart Transplantation Committee was officially created on July 1, 2020, and work before that time was performed by the OPTN Thoracic Organ Transplantation Committee. "Committee" in this proposal means either the Thoracic Committee or the Heart Committee depending on the point in time being referenced. OPTN, Notice of OPTN Policy, Bylaw, and Guidelines Changes, *Creation of OPTN Heart and Lung Committees*, https://optn.transplant.hrsa.gov/media/3721/thoracic-split-policy-notice-march-2020.pdf (Accessed November 22, 2024).

[70] *Proposal to Modify the Adult Heart Allocation System*, December 2016.

[71] *Proposal to Modify the Adult Heart Allocation System*, December 2016, pp. 12-13.

[72] *Proposal to Modify the Adult Heart Allocation System*, December 2016, p.13.

[73] *Proposal to Modify the Adult Heart Allocation System (Public Comment Proposal)*, OPTN Thoracic Organ Transplantation Committee, August 15 – October 15, 2016, https://optn.transplant.hrsa.gov/media/1921/thoracic_adult_heart_allocation_modification_20160815.pdf (Accessed November 22, 2024). *Proposal to Modify the Adult Heart Allocation System (Public Comment Proposal)*, OPTN Thoracic Organ Transplantation Committee, January 25 – March 25, 2016, https://optn.transplant.hrsa.gov/media/1244/08_adult_heart_allocation_part1.pdf (Accessed November 22, 2024).

[74] *Proposal to Modify the Adult Heart Allocation System*, December 2016, p. 13.

Such an influx of waitlist additions could negatively impact the waitlist survival of those already assigned to adult statuses 2 and 3.[75,76]

Based on waitlist additions at adult status 3 using the dischargeable LVAD with discretionary 30 days criterion and status 4 using the dischargeable LVAD without 30 discretionary days criterion, the Committee estimated that about 700 waitlist additions could occur annually involving candidates who might be eligible to transition to statuses 2 or 3 at any time.

Additionally, the Committee members acknowledged that heart failure programs may not register a patient on the waiting list who the program believes is unlikely to receive a transplant based on certain factors, including if the candidate is supported by a dischargeable LVAD.[77,78] If implemented, the proposed policy modifications could encourage heart programs to register such candidates on the waiting list, thus further increasing the number of candidates assigned to statuses 2 and 3. With this in mind, they chose to establish eligibility based on time since LVAD implant rather than since waitlist registration. Implant date avoids disadvantaging patients whose transplant program may not have initially waitlisted them because of the perceived futility of obtaining a transplant. Because a patient can have a durable LVAD implanted as destination therapy, the potential exists for some waitlisted candidates to have accumulated more time since implant than time since registration.

To assist the Committee's discussion, the information in **Table 2** was prepared for the Committee by OPTN contractor staff. The table provides a more precise picture of the estimated number of candidates who would be eligible for each status following an instantaneous change in active adult heart waiting list candidates under the possible LVAD policy options. The table shows that on April 30, 2024, a total of 2,451 candidates were registered on the waiting list, including 229 adult status 2 candidates and 169 adult status 3 candidates. (Temporarily inactive candidates are not included in the table.). The Committee considered several alternative timeframes for eligibility, including status 2 eligibility six years after device implant and status 3 eligibility four years after implant. Other options considered included seven and five years for status 2 and status 3 eligibility, respectively, as well as eight and six years.

Table 2: Example of Changes in Active Adult Heart Waiting List Assignments Under Possible LVAD Priority Policies

Adult Status[a]	Candidate Assignments 4/30/2024	% of Total Candidates Waiting	Candidate Assignments 5+ and 7+ Years After Implant	% of Total Candidates Waiting	Candidate Assignments 6+ and 8+ Years After Implant	% of Total Candidates Waiting
1	19	0.8%	19	0.8%	19	0.8%
2	229	9.3%	297	12.1%	259	10.6%
3	169	6.9%	291	11.9%	237	9.6%
4	1,407	57.4%	1,217	49.7%	1,309	53.4%
5	115	4.7%	115	4.7%	115	4.7%
6	512	20.9%	512	20.9%	512	20.9%
Total	**2,451**	**100.0%**	**2,451**	**100.0%**	**2,451**	**100.0%**

[a] Temporarily inactive candidates are not included in the analysis.

The table further indicates the number of candidates who would be eligible for each status based on the number of years after being registered on the waiting list and after having their LVAD device implanted.

[75] Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee.
[76] Jorde et al., "The Society of Thoracic Surgeons Intermacs 2023 Annual Report."
[77] Meeting Summary for May 11, 2023 meeting, OPTN Heart_IABP Status Subcommittee.
[78] Ambardekar and Hoffman, "Newton's Laws of Heart Transplant Allocation," p. 207.

There was some consensus among Committee members that the appropriate solution (when addressing medical urgency) is to allow LVAD candidates to be assigned to status 3 after four years and status 2 after six years. However, the Committee also agreed that use of the two timeframes would lead to an influx of status 2 and 3 candidates that would negatively impact the waitlist mortality of the candidates already assigned to those statuses. As a result, their interim solution until continuous distribution of hearts is implemented is to start with timeframes of eight years for status 2 eligibility and six years for status 3 eligibility because the candidates waiting the longest are the most likely to develop complications with their LVAD.[79] After that initial group of candidates has transitioned to statuses 2 and 3, then the Committee wants to address the next group of candidates who will have been waiting the longest. If the Committee determined the waitlist mortality of the candidates already assigned to statuses 2 and 3 was being negatively impacted by the changes, they could take steps to prevent implementation of the next phase.

For comparison purposes, the table also indicates the number of candidates who would be eligible for statuses 2 and 3 at five- and -seven years after device implant and after six- and eight-years after implant. As shown in the table, implementing a policy proposal making LVAD candidates eligible for status 3 five-years after implant date would increase the number of status 3 candidates from 169 to 291, an increase of 72%. Similarly, granting status 2 eligibility to candidates waiting at least seven years after device implant would increase the number of candidates from 229 candidates to 297 candidates, a 30% increase.

In contrast, implementing the proposed policy change using six- and eight-years after implant results in fewer total candidates transitioning to statuses 2 and 3, and presumably putting less pressure on the waitlist mortality of candidates already assigned to the statuses. The number of candidates eligible for status 3 would increase from 169 to 237 based on LVAD candidates who have had their device implanted at least six years. The number of candidates eligible for status 2 assignment would increase from 229 to 259 based on eight years after device implant.

Throughout development of the proposal, the Committee debated the equity of the proposed changes for candidates listed at statuses 2, 3, and 4.[80] During a meeting of the Committee's IABP Status Subcommittee in May 2023, some members cautioned against including status 2 eligibility in what would eventually become the Committee's current proposal. It was said that the purpose of the status 2 criteria is to allocate donor hearts to candidates who are very sick and in need of a transplant.[81] However, not all candidates on LVAD support fit the description of medical urgency that is associated with status 2.[82]

It was said, for example, that the proposed changes take candidates who have been supported by a dischargeable LVAD for eight years and who are presumably doing relatively well and escalates them ahead of patients suffering from device complications or on par with candidates who suffered cardiogenic shock.[83] It was also said that the heart community's response to the changes might be along the lines that the Committee is putting a system in place that prioritizes healthy patient over unwell patients.[84]

[79] Hess et al., "Left Ventricular Assist Device Bridging to Heart Transplantation."
[80] Meeting Summary for May 4, 2023 meeting, OPTN Heart_IABP Status Subcommittee.
[81] Meeting Summary for May 11, 2023 meeting, OPTN Heart_IABP Status Subcommittee, https://optn.transplant.hrsa.gov/media/lxeh0giz/20230511_iabpsubco_meeting-summary.pdf (Accessed November 21, 2024).
[82] Ibid.
[83] Meeting Summary for October 9, 2024 meeting, OPTN Heart Transplantation Committee.
[84] Ibid.

Ultimately, the Committee agreed to move forward using eight and six years after device implant. It was the Committee's strong belief that the smaller number of candidates eligible to transition after eight and six years might have less impact on the waiting list mortality of candidates already assigned to statuses 2 and 3 than if the Committee proceeded using seven and five years to determine eligibility. It was the Committee's strong belief that granting adult status 2 and 3 eligibility to the group of candidates who have been supported by their LVADs for at least eight or six years, respectively, is more appropriate due to their increased risk of experiencing an adverse event than if the Committee proceeded with the seven and five years option.

Inclusion of 'Step-down' in Years of Device Support for Eligibility Is Intended to Prevent Negatively Impacting Waitlist Survival Rates of Existing Status 2 and 3 Candidates

As the Committee considered the potential impact of increased waitlist additions and the appropriate number of years of waiting they decided that moving forward with a phased implementation will avoid such a problem from occurring. While the Committee chose to initially offer status 2 and 3 eligibility based on eight and six years since device implant, they also saw a need to address the group of candidates at seven and five years.

Therefore, approximately 18 months after implementation of the changes, the Committee proposes shortening the eligibility timeframes to seven years for status 2 and five years for status 3. The 18-month interval provides the Committee with the opportunity to review monitoring results six and 12 months after implementation. If the monitoring results indicate positive outcomes, then the step-down in the eligibility timeframes to seven years for status 2 and five years for status 3 are already scheduled to come into play. If the monitoring results indicate the changes are not having the intended impact on the candidate population, the Committee can develop a policy proposal to address the identified shortcomings.

Overview of Proposal

The Committee proposes adding eligibility criteria to *Policy 6.1.B: Adult Heart Status 2 Requirements* and *Policy 6.1.C: Adult Heart Status 3 Requirements*. The new criteria will permit adult candidates supported with a dischargeable LVAD for at least eight years to transition to status 2. Additionally, adult candidates who have been supported for at least six years with a dischargeable LVAD will be eligible for status 3 assignment.

The proposal does not impact the current adult heart status 3 criterion, Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days. Currently, only a small number of patients on dischargeable LVAD support achieve transplant during that brief period of time.

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of the National Organ Transplantation Act of 1984 (NOTA) and the Organ Procurement and Transplantation Network (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."[85] The OPTN Final Rule states that the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[86] The proposed policy change addresses equitable allocation by ensuring similarly

[85] 42 U.S.C. § 274(b)(2)(B).
[86] 42 C.F.R. § 121.4(a)(1).

situated patients receive offers by modifying the eligibility criteria so that adult heart candidates with dischargeable LVADs who have waited at least six years have improved opportunities for receiving donor hearts.[87] Without such additional priority, such candidates are likely to develop complications with the device.[88]

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."[89] This proposal:

- **Is based on sound medical judgement**[90] 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, and research findings that the longer a candidate waits with an implanted LVAD the more likely the candidate is to experience complications associated with the device. Such complications require re-listing at a higher medical urgency status and/or a becoming too sick to remain listed for transplant or to receive a transplant. According to Rali et al., "[a]s patients have more adverse events…they are at increasing risk of delisting or death, a burden that is multiplied by the overall number of adverse events."[91] The Committee believes the proposed step-down approach of reducing the number of years of device support for eligibility reflects sound medical judgment because within the total population of stable LVAD candidates, the risk of experiencing a device complication or malfunction varies by groups based on the amount of time they have been supported by their devices.
    - **Seeks to achieve the best use of donated organs**[92] by ensuring organs are allocated to and transplanted in stable LVAD candidates before they have waited lengthy periods of time, which leads to greater risk of complication.
- **Is designed to avoid futile transplant**[93] because there is no evidence of poorer post-transplant outcomes for candidates who were supported by a LVAD following the changes implemented in October 2018:

[87] Hess et al., "Left Ventricular Assist Device Bridging to Heart Transplantation."
[88] Ibid.
[89] 42 C.F.R. § 121.8(a).
[90] 42 C.F.R. § 121.8(a)(1).
[91] Aniket S. Rali et al., "Changing Strategy Between Bridge to Transplant and Destination LVAD Therapy After the First 3 Months: Analysis of the STS-INTERMACS Database," *Journal of Cardiac Failure* 30, no. 4 (2024): 552–61. https://doi.org/10.1016/j.cardfail.2023.09.011.
[92] 42 C.F.R. § 121.8(a)(2).
[93] 42 C.F.R. § 121.8(a)(5).

    - Recipients transplanted with an LVAD at status 4 had noticeably superior one-year post transplant survival compared to recipients transplanted at more medically urgent statuses 1, 2, and 3.[94]
- **Is designed to…promote patient access to transplantation**[95] by ensuring the use of a dischargeable LVAD:
    - Reflects the level of patient risk for which it was intended and provides certainty a candidate supported by such a device has the appropriate level of access to receive a donor heart offer.
    - Reduces the overutilization of the temporary MCSD and IABP criteria in status 2 when those options are not clinically appropriate provides a meaningful pathway to receiving donor offers and transplantation in a timely manner for stable candidates before experiencing adverse events.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient, and it is specific to an organ type, in this case heart.[96,97]

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[98]
- Promotes the efficient management of organ placement[99]
- Is not based on the candidate's place of residence or place of listing[100]

Transition Plan

The Final Rule requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[101] The Committee does not anticipate that any candidates currently assigned at status 2 or 3 will no longer qualify for those statuses after the initial policy changes are implemented. Following the initial implementation phase granting eligibility based on eight and six of device support, if it appears that candidates assigned to statuses 2 and 3 by other criteria are being experiencing worse waitlist mortality than before, the Committee can take action to prevent implementation of the proposed reduction in eligibility timeframes of status 2 after seven years and status 3 after five years. The Committee can use that time to re-evaluate the effectiveness of the policy changes. The Committee seeks community feedback as to whether there are potential unforeseen circumstances that could result in such candidates no longer qualifying at status 2 or 3.

[94] Bradbrook et. al., "A National Assessment of One-Year Heart Outcomes."
[95] 42 C.F.R. § 121.8(a)(5).
[96] 42 C.F.R. § 121.8(a)(3).
[97] 42 C.F.R. § 121.8(a)(4).
[98] 42 C.F.R. § 121.8(a)(5).
[99] Ibid.
[100] 42 C.F.R. § 121.8(a)(8).
[101] 42 C.F.R. § 121.8(d)(1).

Implementation Considerations

Member and OPTN Operations

This proposal will impact the operations of transplant hospitals and the OPTN but will not affect histocompatibility laboratories or organ procurement organizations.

Operations affecting Transplant Hospitals

OPTN transplant hospital staff will need to be aware of the eligibility changes for status 2 and 3 assignment. Additionally, transplant hospital staff should review the device implant date for each of their candidates supported by a dischargeable LVAD. Transplant hospital staff should use the information to determine whether their candidates are eligible for assignment at status 3 or status 2, and whether such an assignment is appropriate for each eligible candidate. OPTN transplant programs maintain discretion for determining what is clinically appropriate for each of their candidates even if such candidates are eligible for assignment using the proposed policy changes.

Operations affecting the OPTN

The OPTN currently collects the implant date associated with all types of heart mechanical circulatory support devices. The OPTN also collects the explant date associated with each device.

The proposal relies on currently collected OPTN data to determine candidate eligibility. As a result, the proposal is not expected to require submission of OMB-approved data collection forms for OMB approval under the Paperwork Reduction Act of 1995.

The OPTN Board will need to approve sunsetting the six- and eight-year policy changes 18 months following its implementation and establishing the five- and seven-year eligibility requirements.

Potential Impact on Select Patient Populations

Research findings indicate that since the heart allocation changes implemented in October 2018, dischargeable LVAD candidates have had to wait for assignment at status 2 or 3 after experiencing a device complication or device malfunction before receiving donor heart offers.[102] The proposed changes intend to provide such candidates with a meaningful pathway to transplant without having to experience adverse events. As a result, current patterns in donor heart access may change for adult heart status 2, 3, and 4 candidates. Because of the impact on a wide group of candidates, the changes are not expected to provide a disproportionate positive benefit to a specific vulnerable population. Stable, dischargeable LVAD candidates are expected to experience better post-transplant outcomes as a result of being transplanted before their acuity becomes more severe.[103]

The proposal provides a meaningful pathway for adult heart candidates who have been supported by dischargeable LVADs for a determined number of years since device implant to receive increased priority because of the increasing risk of experiencing an adverse event leading to reduced survival.[104]

[102] Hess et al., “Left Ventricular Assist Device Bridging to Heart Transplantation,” pp. 81, 83-84.
[103] Ibid.
[104] Hariri et al., “Long-Term Survival on LVAD Support,” p. 165.

Projected Fiscal Impact

The Fiscal Impact Advisory Group, comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal. The proposal was determined to have a low overall fiscal impact on transplant hospitals. No significant fiscal impacts were recorded for histocompatibility labs or organ procurement organizations.

Projected Impact on Histocompatibility Laboratories

There were no significant fiscal impacts indicated with this proposal.

Projected Impact on Organ Procurement Organizations

There were no significant fiscal impacts indicated with this proposal.

Projected Impact on Transplant Hospitals

This proposal is expected to have a low fiscal impact as new calculations create the status update changes.

Projected Impact on the OPTN

It is estimated that $58,238 is needed for the development of this proposal. Development includes committee preparation and facilitation, proposal development, research and analysis, presentations, compliance evaluation, and data collection requirements. It is estimated that $429,915 would be needed to implement this proposal. Implementation would involve implementation communications and educational materials, updates to OPTN documents, templates, and processes, software engineering, IT project management, analysis, and quality assurance. It is estimated that $49,750 will be needed for ongoing support. Ongoing support will include member support, monitoring, and post-implementation evaluation. The total for development, implementation, and ongoing support is estimated to be $537,903.[105]

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 on at the program." Candidates utilizing this status will be included during routine member surveys and will be evaluated to ensure they meet the status requirements. Any data entered into OPTN computer systems may be reviewed by the OPTN, and members are required to provide documentation as requested.

[105] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

Policy Evaluation

This policy will be formally evaluated at six-, 12-, and 24-months post-implementation. All metrics will be evaluated as data becomes 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 success of this policy will be determined by monitoring the following key metrics:

- Mortality rates for adult heart candidates
- Count of adult status 2 exceptions submitted

If this policy is successful, it is expected that waiting list mortality rates will decline for adult heart candidates with dischargeable LVADs without an increase in waiting list mortality for other adult heart candidates. The number of adult heart Status 2 exceptions is also expected to decrease.

The Committee will also review the following metrics, which will be compared pre- and post-implementation:

- Count of adult heart candidates supported by LVAD elevated to adult status 2 and adult status 3
- Distribution of time spent waiting for adult heart candidates supported by LVADs
- Count and percent of adult heart candidates supported by an LVAD at time of listing
- Count and percent of adult heart candidates supported by an LVAD at time of transplant

Conclusion

The heart transplantation community is concerned that fewer dischargeable LVADs are being used to support adult candidates because the community sees little chance of status 4 candidates being transplanted following the 2018 changes.[106] The proposal provides a pathway for adult status 4 candidates who are supported by a dischargeable left ventricular assist device (LVAD) to transition to status 2 or 3 based on the amount of waiting time since the device was implanted. Specifically, candidates whose devices were implanted at least six years prior will be eligible for status 3. In addition, candidates whose devices were implanted at least eight years prior will be eligible for status 2. The Committee also proposes that 18 months after the policy changes are implemented, the eligibility timeframes will be reduced to seven and five years for assignment at statuses 2 and 3, respectively. The Committee is proposing the changes in order to remove the disincentives to LVAD placement and improve the outcomes of those supported by dischargeable LVADs.

Considerations for the Community

The Committee is requesting feedback about the following:

- The appropriateness of the proposed changes in context of the following:
    - Does clinical evidence support the need to give greater prioritization to candidates who have waited an extended period of time for a transplant?
    - Should stable, non-hospitalized candidates be given the same priority as candidates who experienced stroke, infection, or device malfunction?
    - From the perspective of patients, donors, and their families and caregivers, is the tradeoff between potentially transplanting fewer sicker patients versus transplanting more patients before they get sicker appropriate?

[106] Meeting Summary for October 17, 2019 meeting, OPTN Thoracic Transplantation Committee.

- Should the Committee wait until after the allocation changes associated with the Amend Adult Heart Status 2 Mechanical Device Requirements have been implemented and monitoring results are available before making the proposed changes?
- Should the Committee include the proposed 'step-down' provision granting status 2 and 3 eligibility after seven- and five-years following device implant, respectively, or wait for monitoring results to determine effectiveness before shortening the timeframes?

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.

Policy 6.1.B.vii: Dischargeable Left Ventricular Assist Device (LVAD) Support for Eight or More Years

A candidate's transplant program may assign a candidate to adult status 2 if the candidate has been continuously supported by a qualifying dischargeable LVAD for at least eight years. The OPTN maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 180 days from submission of the *Heart Status 2 Justification Form* as long as the candidate is supported by a qualifying dischargeable LVAD. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 2 Justification Form* as long as the candidate remains supported by a qualifying dischargeable LVAD.

Policy 6.1.C.xiv: Dischargeable Left Ventricular Assist Device (LVAD) Support for Six or More Years

A candidate's transplant program may assign a candidate to adult status 3 if the candidate has been continuously supported by a qualifying dischargeable LVAD for at least six years. The OPTN maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 180 days from submission of the *Heart Status 3 Justification Form* as long as the candidate is supported by a qualifying dischargeable LVAD. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 3 Justification Form* as long as the candidate remains supported by a qualifying dischargeable LVAD.

[Note: Eighteen months after implementation of the aforementioned Policy 6.1.B.vii and Policy 6.1.C.xiv, both policy sections will sunset and the following Policy 6.1.B.vii and Policy 6.1.C.xiv will be effective.]

Policy 6.1.B.vii: Dischargeable Left Ventricular Assist Device (LVAD) Support for Seven or More Years

A candidate's transplant program may assign a candidate to adult status 2 if the candidate has been continuously supported by a qualifying dischargeable LVAD for at least seven years. The OPTN maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 180 days from submission of the *Heart Status 2 Justification Form* as long as the candidate is supported by a qualifying dischargeable LVAD. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 2 Justification Form* as long as the candidate remains supported by a qualifying dischargeable LVAD.

Policy 6.1.C.xiv: Dischargeable Left Ventricular Assist Device (LVAD) Support for Five or More Years

A candidate's transplant program may assign a candidate to adult status 3 if the candidate has been continuously supported by a qualifying dischargeable LVAD for at least five years. The OPTN maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 180 days from submission of the *Heart Status 3 Justification Form* as long as the candidate is supported by a qualifying dischargeable LVAD. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 3 Justification Form* as long as the candidate remains supported by a qualifying dischargeable LVAD.

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