

Notice of OPTN Policy Changes

Escalation of Status for Time on Left Ventricular Assist Device

Sponsoring Committee:	OPTN Heart Transplantation Committee
Policies Affected:	<i>6.1.B.vii: Dischargeable Left Ventricular Assist Device (LVAD) Support for Eight or More Years</i> <i>6.1.C.xiv: Dischargeable Left Ventricular Assist Device (LVAD) Support for Six or More Years</i>
Public Comment:	January 21 – March 19, 2025
Board Approved:	June 9, 2025
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Policy Changes

The purpose of these policy changes is to provide a pathway to higher priority on the waiting list for adult candidates supported by dischargeable left ventricular assist devices (LVADs).¹ This increased priority will result in a higher likelihood of transplantation for those supported by an LVAD, prior to developing a serious complication, and lead to the transplanting of more stable, non-hospitalized candidates and therefore better post-transplant outcomes.

Following the implementation of allocation policy changes in 2018, the use of LVADs as a bridge-to-transplant therapy decreased and fewer LVAD-supported candidates were transplanted.^{2,3,4,5} These decreases are likely caused by the 2018 changes, which defined disease severity based on the heart therapy provided. As a result, transplant programs became incentivized to use therapies associated with higher priority statuses when therapies associated with lower priority statuses may have been equally effective.⁶ Despite the decrease in the utilization of LVADs, evidence continues to suggest that they remain a stable alternative to transplant. However, the risk of stroke, infection, and bleeding increases the longer the device is implanted.^{7,8}

¹ 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.

² 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).

³ Bradbrook et al., "A National Assessment of One-Year Heart Outcomes."

⁴ Barghash et al., "Durable LVADs as a Bridge to Transplantation."

⁵ *Amend 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).

⁶ 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>.

⁷ 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>.

⁸ Hariri et al., "Long-Term Survival on LVAD Support."

These policies address the issues described above by allowing adult heart candidates supported by dischargeable LVADs to be eligible for a transition to statuses 2 or 3 at determined time periods since device implantation. This increased priority will ensure LVAD candidates are able to access transplant in a timely manner, before device complications preclude them from safe transplantation, while balancing the medical urgency of other status 2 and status 3 candidates.

Proposal History

- This proposal was developed in response to the heart allocation policy changes which went into effect in 2018. These changes increased the granularity of adult candidates' prioritization on the waiting list, resulting in shorter median waiting times, while not impacting waiting list mortality or post-transplant outcomes.
- However, the 2018 changes also resulted in decreased use of LVADs as a bridge-to-transplant therapy, causing fewer LVAD candidates to be transplanted.
- To address these issues, these policy changes were developed by the OPTN Heart Transplantation Committee (the Committee), beginning in 2024.
- The proposal was released for public comment from January 21 – March 19, 2025 and approved by the OPTN Board of Directors in June 2025.
- The public comment document outlined a specific 18-month timeframe for the phased implementation of the proposal. However, this timeline was updated in the final proposal approved by the Board, which allows the Committee to recommend a sunset date for phase 1, based on no less than 6 months of monitoring results.

Summary of Changes

- Adult heart candidates supported by dischargeable LVADs for extended periods of time will be eligible to transition to statuses 2 or 3. These transitions will happen over two phases.
- During Phase 1, a candidate whose device has been implanted for at least:
 - Six years will be eligible for status 3
 - Eight years will be eligible for status 2
- During Phase 2, a candidate whose device has been implanted for at least:
 - Five years will be eligible for status 3
 - Seven years will be eligible for status 2
- Based on no less than 6-months of monitoring results, the Committee will recommend a sunset date for Phase 1 and subsequent transition to Phase 2. If the OPTN Board does not take an action within three months from the date of submission of the recommendation, the recommendation will be implemented.

Implementation

Transplant hospitals will need to be aware of the changes and the two implementation phases. They will need to review the device implant dates for each adult candidate supported by a dischargeable LVAD and determine whether changing status assignments is appropriate. There is no expected impact on organ procurement organizations (OPOs) or histocompatibility labs.

The OPTN will be required to update the OPTN Computer System. The two implementation phases will require two separate system updates. Communications about the changes will be provided to OPTN members, as well as educational materials.

Affected Policy Language

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

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: The OPTN Heart Transplantation Committee will recommend a sunset date to the OPTN Board for the changes outlined in the aforementioned Policy 6.1.B.vii and Policy 6.1.C.xiv, based on no less than six months of monitoring results after implementation of the changes. If the recommended sunset date is not approved or amended by the OPTN Board within three months of its submission, the recommendation shall be considered adopted by the OPTN Board. Upon the sunset of the changes above, the following Policy 6.1.B.vii and Policy 6.1.C.xiv will be effective, pending notice to OPTN members and implementation.]

Policy 6.1.B.vii: Dischargeable Left Ventricular Assist Device (LVAD) Support for ~~Eight~~ 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 ~~eight~~ 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 ~~Six~~ 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 ~~six~~ 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.