OPTN

Retrospective Public Comment for Emergency Guidance Document Update

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage

OPTN Heart Transplantation Committee

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Contents

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage

Affected Guidance: *Guidance for Pediatric Heart Exception Requests*
Sponsoring Committee: *Heart Transplantation*
Board of Directors Date: *June 9, 2025*
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Executive Summary

A shortage of pediatric mechanical circulatory support (MCS) devices and the support equipment needed to operate the devices raised potential patient safety concerns that a sub-group of pediatric heart candidates does not have access to the primary support therapy used to manage their conditions.[1,2] On June 9, 2025, the OPTN Board of Directors addressed the issue by approving an emergency action amending the *Guidance for Pediatric Heart Exception Requests*[3] document to provide impacted candidates with a pathway to pediatric heart status 1A by exception. The emergency actions pathway is established in OPTN Management and Membership Policies E.7.[4] The amended guidance states that National Heart Review Board for Pediatrics (NHRB) reviewers should consider the following circumstances when determining whether a pediatric heart candidate with dilated cardiomyopathy (DCM) is eligible for status 1A by exception:

- There is an acknowledged national shortage of ventricular assist devices, supplies, and support equipment for providing MCS therapy to certain pediatric candidates who have failed inotropic support and for whom there are no acceptable alternative devices available,
- The candidate does not meet the size criteria defined in Table 1 of the *Guidance* document, and
- The candidate's clinical condition demonstrates poor systemic perfusion while supported by high-dose inotropes as defined in Table 1 of the *Guidance* document.

[1] Meeting Summary for May 20, 2025 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/2xfpchz4/20250520_heart_committee-meeting-summary-final.pdf (Accessed June 30, 2025).
[2] Meeting Summary for June 3, 2025 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/kqnm4bli/20250603_heart_committee-meeting-summary-final.pdf (Accessed July 8, 2025).
[3] *Guidance for Pediatric Heart Exception Requests,* OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/kzdcojbp/guidance-addressing-the-use-of-pediatric-heart-exceptions.pdf (Accessed August 12, 2025).
[4] OPTN Management and Membership Policies, E.7: Emergency Actions, March 27, 2025, https://optn.transplant.hrsa.gov/media/ndwbjj3f/optn-management-and-membership-policies.pdf (Accessed June 5, 2025).

The guidance update was implemented on June 12, 2025 and will expire on June 11, 2026 without further action. This emergency guidance update is submitted for retrospective public comment in accordance with the OPTN Final Rule and *OPTN Management and Membership Policies E.7*.

Background

Few MCS devices are designed specifically for pediatric candidates suffering from heart failure.[5] In addition, there is only one device approved for use in small children and infants.[6] The device primarily relies on a blood pump located outside of the patient's body and connected to the patient's heart by cannulas. The blood pump's flow is managed by a stationary driving system, also located outside of the body. The stationary driving system is considered bulky and has limited battery life.[7] As a result, a pediatric candidate supported by the device has limited mobility. A more mobile driving system is currently part of a clinical study approved by the U.S. Food and Drug Administration (FDA).[8] The pediatric heart community has raised concerns that the current stationary driver systems are becoming obsolete while at the same time it is unclear when the new system will obtain FDA approval. As a result, there is a national shortage of MCS devices and their supporting components necessary to meet the demands of pediatric heart candidates.

In February 2021, the OPTN implemented a guidance document to assist members of the NHRB for Pediatrics in standardizing their decision-making when reviewing exception requests for certain Status 1A and 1B candidates.[9] Guidance is provided concerning the following pediatric heart diagnoses:

- Dilated cardiomyopathy,
- Restrictive or hypertrophic cardiomyopathy,
- Ventricular heart disease, and
- Coronary vasculopathy allograft and retransplant

The document recommends certain criteria that reviewers should consider when deciding whether to approve or deny an exception request and transplant programs should incorporate into their exception request narratives. The guidance provides clinical information for pediatric DCM candidates who weigh less than five kilograms (kg) or less than 10 kg. The expectation is that dilated cardiomyopathy candidates who weigh 10 kg or more will have an MCS device implanted. The Briefing Paper supporting the guidance document indicates that the primary reason to provide a status 1A exception for pediatric candidates with DCM who weigh 10 kg or more is the presence of contraindications to mechanical circulatory support or that implanting a MCS device would be very high-risk to the candidate.[10]

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[5] ISHLT Press Release, "Experts at ISHLT Report Urgent Need for Pediatric Heart Support Devices," April 27, 2025, https://www.ishlt.org/about/news-detail/2025/04/27/experts-at-ishlt-report-urgent-need-for-pediatric-heart-support-devices (Accessed June 5, 2025).

[6] Oliver Miera et al., "Quality of Life in Pediatric Patients on a Paracorporeal Ventricular Assist Device with a Novel Mobile Driving System," *JHLT Open* 6 (2024): 100125, https://www.jhltopen.org/article/S2950-1334(24)00074-0/fulltext (Accessed June 6, 2025).

[7] Jennifer Conway et al., "First North American Experience with the Berlin Heart EXCOR Active Driver," *The Journal of Heart and Lung Transplantation* 43, no. 11 (2024): 1861–63. https://doi.org/10.1016/j.healun.2024.08.005. (Accessed June 5, 2025).

[8] EXCOR Active Driving System for the EXCOR Pediatric VAD IDE Study, ClinicalTrials.gov ID: NCT05610787, Berlin Heart, Inc., Last Update Posted: 02/08/2023, https://clinicaltrials.gov/study/NCT05610787?term=IDE%23%20G200252&rank=1 (Accessed June 5, 2025).

[9] *Notice of OPTN Guidance: Guidance Addressing the Use of Pediatric Heart Exceptions*, OPTN Heart Transplantation Committee, OPTN Board approved February 9, 2021, https://optn.transplant.hrsa.gov/media/4247/guidance_addressing_use_ped_heart_exceptions_202012.pdf (Accessed July 1, 2025).

[10] *Guidance Addressing the Use of Pediatric Heart Exceptions*, OPTN Heart Transplantation Committee, December 2020, p. 8, https://optn.transplant.hrsa.gov/media/bkbakc2e/bp_202012_guidance_addressing_use_ped_heart_exceptions.pdf (Accessed July 8, 2025).

Purpose

The OPTN Board of Directors approval of the emergency action to update the guidance document addresses circumstances that could reduce certain pediatric candidates access to the primary form of therapy for their clinical condition. No later than 90 days after the update's effective date of June 12, 2025, or by September 10, 2025, the Committee will evaluate the need for the guidance update to remain in effect or whether an expiration date earlier than June 11, 2026 should be established.

The Committee developed this guidance change to provide a temporary exception pathway for pediatric DCM candidates to obtain status 1A priority during an acknowledged shortage of MCS devices and support equipment. According to Conway et al., "[F]or pediatric candidates with end-stage heart failure, the use of ventricular assist devices for recovery or as a bridge to heart transplant is becoming the standard of care."[11] Currently, one such device is the main form of durable support for smaller patients.[12] Given the shortage of such devices, supplies, and companion components, pediatric DCM candidates face limited access to the primary support therapy for their clinical condition. Additionally, transplant programs could not submit exception requests on behalf of such candidates because the guidance did not account for such circumstances. The Committee identified the issue as a potentially significant patient safety risk and addressed the risk by updating NHRB guidance so that impacted pediatric candidates are given the appropriate access to transplant and waitlist priority.[13,14]

Guidance Updates

On June 9, 2025, the OPTN Board of Directors approved an emergency action to update the Guidance for Pediatric Heart Exception Requests. This guidance update does not create or change OPTN policy. It is intended to address an emergent patient safety issue, as well as promote consistency, equity, and efficiency of the pediatric exception request review process.

The guidance is updated to inform NHRB for Pediatrics reviewers that pediatric candidates with DCM, whose clinical condition is not otherwise addressed in the guidance document, may still be eligible for status 1A assignment by exception under the following circumstances:

- There is an acknowledged shortage of pediatric mechanical circulatory support devices and/or the support equipment necessary to support such devices,
- There are no acceptable alternative devices available,
- The candidate does not meet the size criteria described in Table 1 of the guidance, and
- The candidate's clinical condition demonstrates poor systemic perfusion while supported by high dose inotropes as defined in Table 1 of the guidance.

Transplant programs should reference the updated guidance language when completing the clinical narrative of the exception request and describe in detail how the candidate in question is impacted.

NOTA and Final Rule Analysis

This emergency update of the guidance document is authorized by NOTA to "provide information to physicians and other health professionals."[15] Additionally, this guidance will support the ongoing and

[11] Conway et al., "First North American Experience with the Berlin Heart EXCOR Active Driver."
[12] Conway et al., "First North American Experience with the Berlin Heart EXCOR Active Driver."
[13] Meeting Summary for May 20, 2025 meeting, OPTN Heart Transplantation Committee.
[14] Meeting Summary for June 3, 2025 meeting, OPTN Heart Transplantation Committee.
[15] NOTA, 42 U.S.C. §274 (b)(2)(H).

future development of OPTN policies in accordance with the OPTN Final Rule. Establishing and updating guidance for review boards supports emerging issues that may impact current heart allocation and exception policies and can highlight the need for such guidance to become policy in the future.

The OPTN issued this guidance update to support the operation of the NHRB for Pediatrics by ensuring that transplant programs and NHRB reviewers have appropriate clinical guidance regarding the medical criteria to consider when submitting and reviewing exception requests related to pediatric DCM candidates who experience limited access to MCS therapy due to shortages of devices and support equipment. The guidance update will assist in reducing inter-transplant program variance by establishing and documenting the circumstances under which a pediatric DCM candidate should be considered for status 1A priority by exception. Moreover, the update should ensure more consistent decision-making across all NHRB reviewers, while also ensuring transplant programs consistently provide the type of information and level of detail needed for reviewers to make such decisions.

The OPTN Board of Directors is authorized to approve emergency actions according to *OPTN Management and Membership Policy E.7: Emergency Actions*. Under *OPTN Management and Membership Policy E.7*, an emergency action is permissible if it is required due to an emergent public health issue or patient safety factors.[16] The consensus of the Heart Committee members was that an emergency action was required to address the device shortage and emerging patient safety situation.[17,18] As such, the Committee recommended that the OPTN Board of Directors approve the proposed guidance modifications as an emergency action in order for the changes to be implemented as soon as possible. *Management and Membership Policy E.7* requires that emergency actions designate a future date upon which the action will expire. The future date can be no more than 12 months beyond the action's effective date. The emergency action became effective on June 12, 2025, and is scheduled to expire on June 11, 2026. By September 10, 2025, the Committee will determine if the update should remain effective based on whether a device and equipment shortage still exists. Finally, any emergency actions are required to be distributed for public comment no more than six months after approval. This retrospective public comment proposal satisfies this requirement.

Implementation Considerations

The guidance update was communicated by the OPTN to both NHRB for Pediatrics reviewers and transplant programs.

OPTN Actions

The OPTN notified all OPTN members about the emergency guidance update through a targeted communication on June 12, 2025. Current NHRB for Pediatrics educational materials will be updated and shared with reviewers.

Projected Fiscal Impact on the OPTN

This project was implemented on June 12, 2025 at an estimated cost of $(redacted). Implementation included member communications and updates to the OPTN website. It is estimated that $(redacted)

[16] OPTN Management and Membership Policy E.7: *Emergency Actions* (March 27, 2025).
[17] Meeting Summary for May 20, 2025 meeting, OPTN Heart Transplantation Committee.
[18] Meeting Summary for June 3, 2025 meeting, OPTN Heart Transplantation Committee.

will be needed for ongoing support. Ongoing support includes member support and facilitation of committee discussions. The total estimate for implementation and ongoing support is $(redacted).[19]

Member Actions

Transplant programs should educate staff regarding the availability of the updated exception eligibility criteria associated with the shortage of MCS devices and supporting equipment. Programs will also need to review the updated guidance and determine how, if at all, it impacts their pediatric DCM candidates. Transplant program staff will need to be familiar with the circumstances under which an exception request is permissible and the type and detail of the clinical information that should be provided in the exception narrative. NHRB reviewers should be equally familiar with information provided in the guidance update and the circumstances under which it applies.

MCS Device and Support Equipment Shortage Monitoring

OPTN Management and Membership Policy E.7 requires that emergency actions designate a future date upon which the action will expire. This emergency action is scheduled to expire on June 11, 2026. Although this is not policy, it provides updated guidance to assist NHRB for Pediatrics reviewers' decision-making about exception requests involving certain pediatric DCM candidates experiencing limited access to the primary support therapy due to ongoing national shortages. By September 10, 2025, the Committee will evaluate whether there is still a shortage of MCS devices and supporting equipment, such that the expanded guidance remains necessary. If not, the Committee will recommend an expiration date that is earlier than June 11, 2026 to the OPTN Board of Directors.

Conclusion

The emergency action updating the guidance document developed by the Committee and approved by the OPTN Board of Directors assists NHRB reviewers' decision-making involving exception requests for pediatric DCM candidates during times of acknowledged shortages in MCS devices and supporting equipment. Transplant programs should also use the guidance update to ensure the exception request they submit contains the appropriate type of information and level of detail necessary for NHRB reviewers to make informed decisions. A Committee objective of updating the guidance is to ensure that the subset of pediatric DCM candidates experiencing limited access to widely accepted support therapy have their exception requests reviewed consistently by NHRB reviewers. The Committee will review the need for the guidance update to remain in effect no later than 90 days following implementation. The Committee will also monitor the change in the number of status 1A exception requests submitted for pediatric candidates weighing at least 10 kg who have DCM as part of this effort.

Considerations for the Community

The Committee requests feedback concerning the following questions:

- Are the guidance updates approved through the emergency action appropriate for addressing the problem?

[19] 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. Resources estimates are exempted from public disclosure under the Freedom of Information Act exemption 4.

Guidance Document

RESOLVED, that the following emergency action is required due to patient safety factors and is thereby authorized by *OPTN Management and Membership Policy E.7: Emergency Actions*.

FURTHER RESOLVED, that the changes to the *Guidance for Pediatric Heart Exception Requests*, as set forth below, are hereby approved, effective June 12, 2025, and shall expire on June 11, 2026.

FURTHER RESOLVED, that the OPTN Heart Transplantation Committee will re-evaluate the shortage of MCS devices and supporting equipment and recommend to the OPTN Board whether the guidance update needs to remain in effect by September 10, 2025.

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example)

Guidance for Pediatric Heart Exception Requests

Diagnoses addressed in this Guidance

The guidance document was drafted with the goal of helping the members of the National Heart Review Board for Pediatrics standardize decision-making when reviewing exceptions requests for certain Status 1A and Status 1B candidates. The document provides guidance on the following pediatric heart diagnoses:

- Dilated cardiomyopathy
- Restrictive or hypertrophic cardiomyopathy
- ventricle heart disease
- Coronary vasculopathy allograft and retransplant

Standard Information for Inclusion with Pediatric Heart Exception Requests

The following information provides useful guidance for transplant program staff responsible for completing the clinical narrative portion of an initial exception request or an extension exception request on behalf of a pediatric heart candidate. Transplant programs are expected to demonstrate that a candidate has both the medical urgency and potential for benefit comparable to that of other candidates at this status.[20]

Transplant programs are strongly encouraged to submit the following information as part of each exception request:

- Contain specific description of the candidate's current diagnoses and methods of support, inclusive of inotropes and mechanical circulatory support;
    - Describe inotrope escalation and/or failure to wean
- Specifically describe how:
    - The candidate meets the exception criteria, or
    - Why standard therapies may not be ideal for the candidate and why the candidate's condition is not addressed by the pre-specified exception criteria
    - Describe why the current policy does not adequately account for the candidate's particular situation and high risk of waitlist mortality
    - Provide timing of symptom changes in relation to exception request

This resource is not OPTN Policy, so it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or to define a standard of care. This resource is intended to provide guidance to transplant programs and the National Heart Review Board.

Category 1: Dilated Cardiomyopathy Patients

Most candidates with dilated cardiomyopathy, in the absence of specific criteria below, are appropriately categorized based on the need for inotropes as Status 1B or for mechanical circulatory

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

support as Status 1A. Table 1 provides useful guidance for the review board asked to approve upgraded listing urgency by exception for children with dilated cardiomyopathy.

Table 1: Recommended criteria for status exceptions

If the candidate has dilated cardiomyopathy and meets this criteria:	Then the candidate may be eligible for:
Is admitted to the transplant hospital that registered the candidate on the waiting list and meets *all* of the following criteria: • Weighs less than 5kg • Supported by *one* of the following with either an escalation from lower dosage or a failure to wean from listed dose: o 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 o 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	Status 1A exception
Is admitted to the transplant hospital that registered the candidate on the waiting list and meets *all* of the following criteria: • Weighs less than 10kg • Supported by *one* of the following with either an escalation from lower dosage or a failure to wean from listed dose: o 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 o 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 • Has poor systemic perfusion as evidenced by *any* of the following: o Need for non-invasive positive pressure ventilation o Feeding intolerance requiring total parenteral nutrition o A decline in end-organ function (e.g. Acute kidney injury)	Status 1A exception

In the event of a recognized national shortage of mechanical circulatory support (MCS) devices and/or a national shortage of the equipment necessary to operate such MCS devices and no acceptable alternative is available, then candidates not meeting the above size criteria, but whose clinical condition is evidenced by poor systemic perfusion while supported by high-dose inotropes as defined in Table 1, may be eligible for status 1A by exception.

Among older and larger patients, the primary reason to provide a 1A exception should be the

presence of contraindications to mechanical circulatory support. Such contraindications are often subjective and based on center experience. However, among the relevant considerations (even in the adolescent population who are overall likely to do well with a VAD) are: recurrent or severe gastrointestinal bleeding, recent or recurrent embolic or hemorrhagic stroke, dialysis-dependent patients requiring simultaneous heart-kidney transplant, hypercoagulable disorder, or the presence of a mechanical prosthetic valve.

Of note, given that there are no reliable predictors of RV failure after LVAD placement in pediatric patients, the concern for the need for biventricular support would not generally be deemed a contraindication to VAD placement.

Category 2: Restrictive or Hypertrophic Cardiomyopathy Patients

Patients with restrictive and hypertrophic cardiomyopathy may have higher mortality on the waitlist when not receiving Status 1A exceptions. The following table (Table 2) provides useful guidance for the review board when evaluating exception requests for candidates with these diagnoses.

Table 2: Recommended criteria for status exceptions

If the candidate has restrictive or hypertrophic cardiomyopathy and meets this criteria:	Then the candidate may be eligible for:
Is admitted to the transplant hospital that registered the candidate on the waiting list and meets *any* of the following criteria: • Supported by *one* of the following with either an escalation from lower dosage or a failure to wean from listed dose: o 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 o 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 • Has had an episode of sudden death or recurrent prolonged runs of hemodynamically significant arrhythmia that are not controlled by medical therapy • Has had syncopal episodes felt to be related to restricted ventricular filling • Has evidence of increased pulmonary vascular resistance (exceeding 6 WU*m^2)	Status 1A exception

Category 3: Single Ventricle Heart Disease

Patients with congenital heart disease are not generally disadvantaged by the current allocation system, where they receive 1A status as long as they are admitted and supported on continuous

inotrope infusions. However, because certain single ventricle adult transplant candidates have had an increase in status (adult Status 4 [equivalent to pediatric 1B] for all congenital patients, with increased status assignments under specific circumstances), this has resulted in the incongruous circumstance where the same patient will have lower listing status as a child (< 18 years old) than as an adult (≥ 18 years).

Accordingly, it appears appropriate to consider more urgent listing for many patients with single ventricle congenital heart disease, even where not supported by inotropes as an inpatient.

To provide more congruity between adult and pediatric listings, the following table should assist the National Heart Review Board members with evaluating exception requests for single ventricle congenital heart disease patients:

Table 3: Recommended criteria for status exceptions

If the candidate has single ventricle congenital heart disease and meets this criteria:	Then the candidate may be eligible for:
Is admitted to the transplant hospital that registered the candidate on the waiting list and is experiencing complications related to their congenital heart disease (including but not limited to: protein-losing enteropathy, plastic bronchitis, or Fontan circuit thrombosis), and is actively receiving therapy for said complication, without regard for change in the candidate's cardiac support	Status 1A exception
Has been palliated through a Fontan procedure, is listed for heart transplantation, and has ongoing complications of the Fontan (including, but not limited to: protein-losing enteropathy, plastic bronchitis, or Fontan circuit thrombosis) and is actively receiving therapy for said complication but does not require hospital admission.	Status 1B exception

Category 4: Coronary Allograft Vasculopathy and Retransplantation

Patients with a prior transplant do not have specific criteria within policy for qualifying for an urgency status higher than Status 2. However, many patients with coronary allograft vasculopathy develop a significant component of restrictive physiology and may not benefit from inotropes. Many patients with coronary allograft vasculopathy may have poor outcomes and a high-risk for sudden cardiac death without significant systolic dysfunction.

Per policy, all patients must be admitted to the hospital where registered to be eligible for Status 1A exception.[21]

[21] OPTN, 6.4 Adult and Pediatric Status Exceptions. Accessed October 27, 2020. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

97 **Table 4: Recommended criteria for status exceptions**

If the candidate has a prior heart transplant and evidence of chronic rejection or significant coronary allograft vasculopathy and meets this criteria:	Then the candidate may be eligible for:
A history of recent cardiac arrest, or signs or symptoms placing patients at high-risk for sudden cardiac death, including any of the following: • A diagnosis of severe CAV similar to ISHLT CAV 3[22] • Significant restrictive hemodynamics • Non-sustained ventricular tachycardia • Unexplained syncope • Inotrope dependence	Status 1A exception
A history of revascularization (either surgical or transcatheter) for coronary allograft vasculopathy	Status 1B exception

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[22] Mehra, Mandeep R, Crespo-Leiro, Maria G, Dipchand, Anne, Ensminger, Stephan M, Hiemann, Nicola E, Kobashigawa, Jon A, Madsen, Joren, Parameshwar, Jayan, Starling, Randall C, and Uber, Patricia A. "International Society for Heart and Lung Transplantation Working Formulation of a Standardized Nomenclature for Cardiac Allograft Vasculopathy—2010." The Journal of Heart and Lung Transplantation 29, no. 7 (2010): 717-27.