Department of Veterans Affairs **VHA DIRECTIVE 1102.08**
Veterans Health Administration **Transmittal Sheet**
Washington, DC 20420 **April 19, 2019**

HEART FAILURE TREATMENT UTILIZING A VENTRICULAR ASSIST DEVICE OR TOTAL ARTIFICIAL HEART: PATIENT SELECTION AND FUNDING

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides the policy for the use and funding of Ventricular Assist Device (VAD) therapy for destination and bridge to transplantation and Total Artificial Heart (TAH) therapy for bridge to transplantation, including guidelines for patient selection**.**

2. SUMMARY OF MAJOR CHANGES: Changes to this directive include the following:

a. Added oversight responsibilities for the Under Secretary for Health and The Deputy Under Secretary for Operations and Management (see paragraph 5, Responsibilities).

b. Added responsibilities for the Health Care team who performs pre-procedural evaluation, the implantation of the VAD or TAH device, and subsequent follow-up care and treatment for the Veteran (see paragraph 5, Responsibilities).

c. Added Training paragraph, specifying that there is no mandatory training requirement (see paragraph 8).

d. Added Records Management paragraph (see paragraph 9).

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The VHA National Surgery Office (NSO) (10NC2) is responsible for the contents of this directive. Questions may be referred to the National Director of Surgery at 202-461-7130.

5. RESCISSIONS: VHA Directive 2012-033, Heart Failure Treatment Utilizing a Ventricular Assist Device or Total Artificial Heart: Patient Selection and Funding, dated November 9, 2012, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2024. This directive will continue to serve as national VHA policy until it is recertified or rescinded.

CERTIFIED BY:	BY DIRECTION OF THE UNDER SECRETARY FOR HEALTH:
/s/ Renee Oshinski Acting Deputy Under Secretary for Health for Operations and Management	/s/ Renee Oshinski Acting Deputy Under Secretary for Health for Operations and Management

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy for the use and funding of Ventricular Assist Device (VAD) and Total Artificial Heart (TAH) for destination therapy and bridge to transplantation therapy, including guidelines for patient selection. **AUTHORITY:** Title 38 Unites States Code (U.S.C.) 7301(b). ***NOTE:*** *This policy does not apply to temporary VAD placement for failure to wean from cardiopulmonary bypass during a scheduled or emergency cardiac surgery procedure (termed post cardiotomy) or to the placement of a percutaneous left VAD in the cardiac catheterization laboratory.*

2. BACKGROUND

a. Heart transplantation is an established treatment modality to cure the symptoms of heart failure and to prolong life. Unfortunately, far more people are waiting for heart transplantation than can be accommodated by the current donor availability. Moreover, not all patients with failing hearts are eligible for transplantation based on age and co-morbidity. The result is a significant number of Veterans with heart failure refractory to medical therapy that would benefit from VAD or TAH therapy.

b. VAD and TAH implantation has been shown to improve the survival, quality of life, and functional capacity in patients with heart failure who are unresponsive to medical therapy. Following implantation and recovery, patients are often discharged from the hospital, regardless of whether the VAD is placed as destination therapy or as a bridge to transplantation.

3. DEFINITIONS

a. **Bridge to Transplantation.** Bridge to transplantation refers to use of a VAD or TAH to support cardiac function in preparation for a heart transplant.

b. **Destination Therapy.** TAH/VAD destination therapy is a therapy intended to support the patient's condition for the remainder of the patient's life or until recovery. ***NOTE:*** *The patient who is not deemed a candidate for a heart transplant and receives a VAD for destination therapy may over time improve and subsequently undergo heart transplantation.*

c. **Health Care Team.** The Health Care Team are those providers performing the pre-procedural evaluation, the VAD or TAH implantation, and establishing a post-procedural care plan.

d. **Total Artificial Heart.** A TAH is a mechanical pump that is surgically implantable to replace both the pulmonary and peripheral circulatory function of the patient's failing heart. Alternatively, two VADs (bi-VAD) can be implanted to support the right side and left side of the heart for similar purpose. ***NOTE:*** *Removal or failure of the TAH device*

results in death. Patients receiving a TAH may be discharged home or remain hospitalized until heart transplantation is performed.

e. **Ventricular Assist Device.** A VAD is a surgically implantable device that is designed to support the circulatory function of the patient's failing heart.

4. POLICY

It is VHA policy that VAD and TAH therapies are provided to eligible Veterans at Department of Veterans Affairs (VA) Cardiac Transplant Centers and VA medical facilities with cardiac surgical programs approved to provide those therapies.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive for each of the Veterans Integrated Services Networks (VISN).

(2) Ensuring that each VISN Director has the sufficient resources to implement this directive in all VA medical facilities with cardiac surgical programs approved to provide those therapies within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **VHA Chief Financial Officer.** VHA Chief Financial Officer is responsible for:

(1) Providing specific purpose funding to the National Surgery Office (NSO) at the approved funding level for that fiscal year to support the complex infrastructure required to sustain VA Cardiac Transplant Centers and VA medical facilities with cardiac surgical programs approved for VAD or TAH implantation by the Under Secretary for Health. Specific purpose funds may not be used to purchase non-VA Community Care or to offset the cost of the device itself. ***NOTE:*** *See paragraph 10, References, for citations to directives with more information about ensuring appropriate usage of funds.*

(2) Ensuring specific purpose funds are not used for the cost of the VAD or TAH device, or the care and treatment of the Veteran receiving either a VAD or TAH when the implantation is performed through Community Care. ***NOTE:*** *The VA medical facility Director, VISN Director, or designee, may elect to provide care and treatment to the Veteran at a non-VA medical facility through Community Care. However, once the Veteran has been determined to be eligible and accepted for care and treatment at a VA medical facility, VA assumes the costs of maintenance of the VAD or TAH, including disposable accessory equipment or replacement of the device if clinically indicated.*

d. **Director, National Surgery Office.** The Director, NSO is responsible for:

(1) Providing oversight to the in-house VHA cardiac surgery programs and the VA Transplant Program, per VHA Handbook 1102.01, National Surgery Office, dated January 30, 2013.

(2) Establishing a database for tracking Veterans who have undergone VAD or TAH implantation by a VA Cardiac Transplant Center or VA medical facility with a cardiac surgical program approved for VAD or TAH implantation by the Under Secretary for Health.

(3) Monitoring patient outcomes according to the requirements of VHA Handbook 1102.01.

(4) Maintaining a list of VA Cardiac Transplant Centers and VA medical facilities with cardiac surgical programs approved for VAD or TAH implantation by the Under Secretary for Health. ***NOTE:*** *VA medical facilities with a cardiac surgery program may be approved for VAD for destination therapy in accordance with VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016. Such approved cardiac surgery programs may not implant VAD or TAH devices as a bridge to transplant.*

(5) At least quarterly, administering and providing distribution of specific purpose funds to VA Cardiac Transplant Centers and VA medical facilities with cardiac surgical programs approved for VAD or TAH implantation by the Under Secretary for Health. ***NOTE:*** *See paragraph 10, References, for citations to directives with more information about approval criteria for VAD and TAH programs and auditing responsibilities related to distribution of specific purpose funds and approval criteria.*

e. **Veterans Integrated Services Network Director.** Each VISN Director must ensure that necessary and appropriate health care is provided to all enrolled or otherwise eligible Veterans, as defined in 38 CFR 17.38.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring VA Medical Facility compliance with this directive

(2) Maintaining the necessary resources and infrastructure complexity to support the Veteran with a failing heart before and after VAD or TAH implantation. ***NOTE:*** *See paragraph 10, References, for citations to directives with more information about regarding maintaining appropriate infrastructure complexity.*

g. **Chief of Staff.** The Chief of Staff is responsible for ensuring:

(1) Patients are provided all the care included in the VA medical benefits package.

(2) The Health Care Team fulfills their responsibilities as delineated in this directive.

h. **Chief of Surgery at a VA Medical Facility Approved for VAD or TAH Implantation.** The Chief of Surgery at a VA medical facility with an approved VAD or TAH program is responsible for ensuring:

(1) VA medical facility has the appropriate infrastructure complexity including qualified cardiac surgery providers, cardiology support staff and intensive care expertise, and resources to provide care and treatment of the Veteran with a failing heart before and after VAD or TAH implantation.

(2) The Health Care Team fulfils their responsibilities as delineated in this directive.

i. **Health Care Team.** The Health Care Team is responsible for:

(1) Ensuring the Veteran meets all the criteria for VAD or TAH implantation as outlined in paragraph 6 before approving the Veteran for the relevant procedure.

(2) Ensuring patient information is submitted as requested by the NSO for the tracking database (see paragraph 5.d.(2)) prior to or following VAD or TAH implantation.

(3) Ensuring a plan for future urgent care of the patient is in place, as outlined in paragraph 7.

(4) Ensuring the medical record contains clear documentation of any handoff of care to a referring VA medical facility, including the name of the accepting and responsible referring medical facility provider, if and when, the Veteran with a VAD or TAH is discharged from the VA Cardiac Transplant Center or VA medical facility with a cardiac surgical program approved for VAD or TAH implantation by the Under Secretary for Health.

6. CANDIDATES FOR VAD AND TAH THERAPY

This paragraph addresses the foundational criteria for initial eligibility; however, each approved program may have additional unique clinical/psychosocial criteria. Referring VA providers may contact the Mechanical Circulatory Assist Device Program directly to refer a patient or for information regarding patient selection criteria; contact information for each program is available here: http://vaww.dushom.va.gov/DUSHOM/surgery/docs/MCAD_Contacts_Listing.docx.
NOTE: *This is an internal VA Web site that is not available to the public.*

a. **VAD for Destination Therapy.** Candidates for VAD implantation for destination therapy must meet the following conditions:

(1) Documented age or co-morbid condition that precludes the patient from being a heart transplant candidate;

(2) Classified by the New York Heart Association (NYHA) as Class IV, advanced-stage heart failure (https://manual.jointcommission.org/releases/TJC2016A/DataElem0439.html).

(3) Refractory to optimal medical management for at least 45 of the last 60 days prior to the VAD implantation, or intra-aortic balloon pump (IABP) dependent for 7 days, or intravenous inotrope dependent for 14 days;

(4) Documented left ventricular ejection fraction (LVEF) of less than (<) 25 percent; and

(5) Demonstrated functional limitation with a peak oxygen consumption of < 14 milliliters (ml)/ kilogram (kg)/minute (min) unless IABP or inotrope dependent, or physically unable to perform this diagnostic test.

NOTE: *The Veteran who receives a VAD for destination therapy that later improves remains eligible for consideration for heart transplantation by a VA Cardiac Transplant Center.*

b. **VAD for Bridge to Transplant**. Candidates for VAD for bridge to transplantation must meet the following conditions:

(1) Approved for and currently listed by a VHA heart transplant program as a candidate for heart transplantation with the United Network for Organ Sharing (UNOS); and

(2) Meet the clinical criteria for VAD placement as a Bridge to Transplant, established by the VHA heart transplant program.

c. **Total Artificial Heart**. Candidates for TAH implantation must meet the following conditions:

(1) Approved for, and currently listed by a VHA heart transplant program as a candidate for heart transplantation with the UNOS;

(2) Classified by NYHA as Class IV, advanced-stage heart failure;

(3) Dependent upon IABP or intravenous inotrope therapy; and

(4) Untreatable with a single VAD alone.

7. DISCHARGE PLANNING AND FOLLOW-UP CARE

a. Each patient discharged following VAD or TAH implantation must have in place a plan for future urgent care that addresses duties and responsibilities for the referring VA medical facility and the VA medical facility implanting the device. The plan must be documented in the medical record prior to VAD or TAH implantation.

b. Each Veteran with an implanted VAD or TAH must be given written instructions for device management by their provider to include a 24 hours a day, 7 days a week (24/7) contact number for the implanting VA medical facility, and be informed of the following:

(1) After the Veteran is discharged home, in the event the Veteran requires immediate medical attention, the Veteran or caregiver must call 911 and activate the community emergency medical treatment system;

(2) If stable for transport, the Veteran should present to the referring VA medical facility for evaluation, and the implanting VA medical facility must be contacted by the VA medical facility where the Veteran presents (given a 24/7 contact number) for further management instruction.

c. Further care and treatment of the Veteran may require transfer to either the VA medical facility that implanted the device, an established VA medical facility approved for VAD implantation, or a Community Care medical facility with appropriate expertise based upon the clinical circumstances of the Veteran. ***NOTE:*** *For further information on transfers between VA medical facilities, see VHA Directive 1094, Inter-Facility Transfer Policy, dated January 11, 2017.*

8. TRAINING

There are no formal training requirements associated with this directive.

9. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

10. REFERENCES

a. 38 U.S.C. 7301(b).

b. 38 CFR 17.38.

c. VHA Directive 1043, Restructuring of Clinical Programs, dated November 2, 2016.

d. VHA Directive 1094, Inter-Facility Transfer Policy, dated January 11, 2017.

e. VHA Directive 2010-018, Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures, dated May 6, 2010.

f. VHA Directive 1601, Non-VA Medical Care Program, dated January 23, 2013.

g. VHA Handbook 1102.01, National Surgery Office, dated January 30, 2013.

h. Cook JA, Shah KB, Quader MA et al. The Total Artificial Heart. *Journal of Thoracic Disease*. 2015. 7(12):2172-2180.

i. Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and

Destination Therapy (CAG-00432R2). Available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=268.

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k. Hurst, J.W., Morris, D.C., Alexander, R.W. The Use of the New York Heart Association's Classification of Cardiovascular Disease as Part of the Patient's Complete Problem List. Clinical Cardiology. 1999. 22: 385-390.

l. National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9), the Centers for Medicare and Medicaid Services. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ncdver=1&DocID=20.9.1&bc=gAAAAAgAAAAAAA%3d%3d&.

m. Slaughter, M.S., Rogers, J.G., Milano, C.A., et al. Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. New England Journal of Medicine 2009. 361: 2241-2251.

n. Specification Manual for Joint Commission National Quality Measures. Available at: https://manual.jointcommission.org/releases/TJC2016A/DataElem0439.html.

o. Veterans Administration-National Surgery Office (NSO) Mechanical Circulatory Assist Device (VAD/TAH) Contact Listing. Available at: http://vaww.dushom.va.gov/DUSHOM/surgery/docs/MCAD_Contacts_Listing.docx.
NOTE: *This is an internal VA Web site that is not available to the public.*