CMS & TJC Updates

Prepared September 2022

The Centers for Medicare & Medicaid Services (CMS)

On 12/1/2020 CMS updated the National Coverage Determination (NCD) for VADs and eliminated the NCD for Artificial Hearts and will defer to standard process where coverage decisions are made by local Medicare administrative contractors. Effective 7/21/2021

Old VAD NCD

NCD - Ventricular Assist Devices (20.9.1) (cms.gov)

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)

The VADs used for bridge to transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:

- The patient is approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.
- The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center under which the patient is listed prior to implantation of the VAD.

3. Destination Therapy (DT) (effective for services performed on or after October 1, 2003)

Destination therapy (DT) is for patients that require mechanical cardiac support. The VADs used for DT are covered only if they have received approval from the FDA for that purpose.

Patient Selection (effective November 9, 2010):

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:

- Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,
- Have a left ventricular ejection fraction (LVEF) < 25%; and,
- Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

Facility Criteria (effective October 30, 2013):

Facilities currently credentialed by the Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure as DT under section 1862(a)(1)(A) of the Social Security Act (the Act):

Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

- A palliative care specialist;
- A social worker;
- A VAD program coordinator;
- At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs; and clinical competence in the management of patients before and after heart transplant;
- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs as BTT or DT, over the course of the previous 36 months with activity in the last year.

The team must include, at a minimum:

New VAD NCD

NCD - Ventricular Assist Devices (20.9.1) (cms.gov)

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

2. Left ventricular assist devices (LVADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
- Are inotrope dependent

  OR

  have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
  - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
  - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.
- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

Facilities must be credentialed by an organization approved by CMS. The process for organizations to apply for CMS approval to be designated as a credentialing organization for LVAD facilities is posted on our web site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html

Current CMS National Coverage Determination

- NYHA Class IV heart failure; and
- Left ventricular ejection fraction ≤25%; and
- Are inotrope dependent
  OR
  Have a Cardiac Index <2.2 L/min/m2, while not on inotropes, and also meet one of the following:
  - Are on optimal medical management based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
  - Have advanced heart failure for at least 14 days and are dependent on an IABP or similar temporary mechanical circulatory support for at least 7 days

Removed:

- DT v BTT Criteria
- VO2 ≤14ml/kg/min or IABP

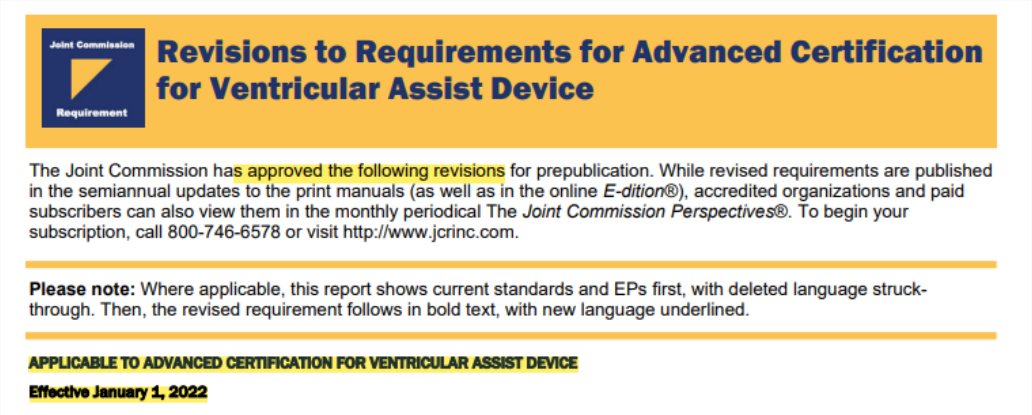
Added:

- CI measurements if not inotrope dependent

Remained:

- Core team members and Surgeon case requirement (10 in past 36 months with activity in past year)

The Joint Commission: Standards revised effective January 1, 2022



Joint Commission Requirement

Revisions to Requirements for Advanced Certification for Ventricular Assist Device

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online *E-dition*®), accredited organizations and paid subscribers can also view them in the monthly periodical The *Joint Commission Perspectives*®. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO ADVANCED CERTIFICATION FOR VENTRICULAR ASSIST DEVICE

Effective January 1, 2022

Revisions in all 6 groups of Standards:

- Certification Participation Requirements (CPR)
- DSPM management
- DSDF Delivering or Facilicating Clinical Care
- DSSE
- DSCT Clinical Information Management

The following slides are not a comprehensive list of all changes. They are annotated for brevity.
The standards no longer specify ‘destination therapy’. It is removed throughout the standards document.

DSPR 3. 3. The program identifies its target population

a. The program utilizes an interdisciplinary approach in determining which patients are eligible for VAD placements.

The following patient criteria are included in this determination:

- New York Heart Association (NYHA) Class IV heart failure; and
- Left ventricular ejection fraction (LVEF) less than or equal to 25%; and
- Inotrope dependent; or
- Cardiac Index (CI) less than 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
- Are on optimal medical management, based on current heart failure practice guidelines for least 45 out of the last 60 days and are failing to respond; or
- Have advanced heart failure for at least 14 days and are dependent on an intraaortic balloon pump or similar temporary mechanical circulatory support for at least 7 days

DSPR.1. The program defines its leadership roles:

4. The program leader(s) identifies, in writing, the composition of the interdisciplinary team.
b. …the interdisciplinary VAD team includes, but is not limited to, the following:
- One or more cardiologist (s)
- One or more cardiothoracic surgeon(s)
- VAD coordinator
- Social worker
- Anesthesiologist(s) or certified registered nurse anesthetist(s)
- Advanced practice provider(s) (if utilized by the program)
- Nursing Staff

7. The program leader(s) makes certain that practitioners practice within the scope of their licensure, certification, training, and current competency
a. The program makes certain that licensed practitioners who manage VAD device settings and parameters are trained, experienced, and privileged according to their scope of practice and in accordance with laws and regulations and organizational procedure(s).
b. The cardiothoracic surgeon(s) is privileged by the organization for VAD implantation.
c. The cardiologist(s), including the heart failure specialist, is privileged by the organization to care for the VAD patient population.

DSPR 4. The services provided by the program are relevant to the target population

a. The program has a referral process to a heart transplant center, if needed.

Removed:
provides a documented heart transplant consultation for each patient.

Note: The exception to this requirement would be those patients who are INTERMACS level 1 or 2 or too clinically unstable for an evaluation to occur

DSPR.5 The program determines the care, treatment, and services it provides.

- Devices are US Food and Drug Administration (FDA) approved and are used according to FDA-approved labeling instructions.
- 24/7 call is now not just to support patients and family but also other caregivers and health care providers

DSDF.1 Practitioners are qualified and competent

~~***Requirement Specific to Ventricular Assist Device Destination Therapy***~~

~~a. The interdisciplinary team has at least the following experience and expertise:~~
~~- One or more cardiologists, each of whom:~~
~~i. Is trained and experienced in advanced heart failure therapies~~
~~ii. Has recent experience managing patients who have had ventricular assist devices placed or heart transplants~~
~~iii. Has sufficient competency in evaluating patients for transplant as evidenced by having worked in or trained in a transplant center~~
~~- One or more cardiac surgeons, each of whom has successfully placed 10 ventricular assist devices in the last 36 months with current activity occurring in the last year~~
~~Note 1: Acceptable ventricular assist device procedures include placement of long-term devices and devices that are part of studies for US Food and Drug Administration approval.~~
~~Note 2: If a surgeon on the team has not placed 10 ventricular assist devices during the required time period, the volume requirement can include artificial heart placements for no more than 50% of the total volume within the 36-month period.~~
~~Note 3: The 10 ventricular assist devices implanted by a surgeon-in-training could have occurred during a training program if the following are met: (1) There is evidence that the surgeon-in-training physically implanted each ventricular assist device under the supervision of a cardiac surgeon. An example would be a procedure log with supporting documentation from the supervising surgeon. (2) The surgeon-in-training participated in the preoperative planning and postoperative management of the patient.~~
~~- A VAD coordinator who has experience and expertise in the complete course of treatment of a VAD patient~~
~~Note: Examples of a VAD coordinator include registered nurse, perfusionist.~~
~~- A social worker who has experience in the assessment and evaluation of a VAD patient and his or her family~~
~~- A palliative care representative who has experience with the VAD patient population~~

MOVED!

- Surgeon volume requirement (10 VADs in last 36 months with activity in past year.)
- No longer a standard
- It is a **Condition of Participation**. Meaning- **<u>to qualify for a TJC site survey you must be meeting the surgeon volume requirement</u>**

<u>The Federal Public Health Emergency (COVID) has temporarily suspended some requirements. This may or may not apply to your center, please check local regulations</u>

DSDF 2 The program develops a standardized process originating in clinical practice guidelines (CPGs) or evidence-based practice to deliver or facilitate the delivery of clinical care

2.

a. The program follows current clinical practice guidelines for advanced heart failure and VAD treatment such as those set forth by the American College of Cardiology (ACC), the American Heart Association (AHA), the Heart Failure Society of America (HFSA), and/or the International Society for Heart and Lung Transplantation (ISHLT). Note: Individual patient needs or newly published evidence may warrant the use of additional clinical practice guidelines.

DSDF 3. The program is implemented through the use of clinical practice guidelines selected to meet the patient's needs

2. .

The patient is evaluated post-implant at least annually to determine further treatment options (such as myocardial recovery or heart transplant eligibility).

DSDF 6. The program initiates discharge planning and facilitates arrangements for subsequent care, treatment, and services to achieve mutually agreed upon patient goals

a. Members of the interdisciplinary team are available to other practitioners managing the patient, as needed, after discharge from the program.
b. The program **documents and implements** a plan to inform and provide education resources to first responders within the vicinity of the patient's residence.

DSSE 3 The program addresses the patient's education needs

a. The program educates the patient and family on troubleshooting the VAD, responding to alarms, and when to seek medical care.