



Management of Heart Failure with the Use of Ventricular Assist Devices (VADs)

Medicare Evidence Development and Coverage Advisory Committee Meeting

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*Centers for Medicare & Medicaid Services
Center For Clinical Standards and Quality
Coverage and Analysis Group
Division of Medical and Surgical Services*

Medicare National Coverage Determination (NCD)

- Titled “Artificial Hearts and Related Devices” (Section 20.9 of the NCD manual 100-03)
- Policy encompasses
 - VADs (postcardiotomy, bridge-to-transplant, destination therapy)
 - Artificial hearts (bridge-to-transplant, destination therapy)

Definition: Ventricular Assist Device

“A ventricular assist device (VAD) or left ventricular assist device (LVAD) is surgically attached to one or both intact ventricles and is used to assist a damaged or weakened native heart in pumping blood.”

VADs for Bridge-to-Transplant

- Device FDA-approved for bridge-to-transplant
- Patient is listed for heart transplant
- Written permission from listing transplant center required if VAD implanted at different center

VADs for Destination Therapy

- Device FDA-approved for destination therapy
- Facility criteria
 - At least one team member with experience implanting 10 VADs or artificial hearts over previous 36 months
 - Membership in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)
 - Certification by The Joint Commission
 - Staff and procedures in place for appropriate informed consent

VADs for Destination Therapy (cont.)

Patient Selection:

- New York Heart Association (NYHA) Class IV chronic end-stage heart failure
- Not candidate for transplant
- Meet specific clinical criteria
 - Failed to respond to optimal medical management for at least 45 of last 60 days, or balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days
 - Left ventricular ejection fraction (LVEF) <25%
 - Functional limitation with peak oxygen consumption ≤ 14 mL/kg/min unless balloon pump-dependent, inotrope-dependent, or physically unable to perform test

Voting Scale

<i>1</i> <i>Low</i> <i>Confidence</i>	<i>2</i>	<i>3</i> <i>Intermediate</i>	<i>4</i>	<i>5</i> <i>High</i> <i>Confidence</i>
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Voting Question 1

How confident are you that there is adequate evidence that specific patient criteria can be used to prospectively identify clinically meaningful changes in health outcomes (improved, equivalent or worsened) that are likely to be experienced by patients who receive a VAD in addition to optimal medical therapy compared with optimal medical therapy alone?

Health Outcomes of Interest

- Clinically meaningful changes in:
 - Mortality
 - Adverse events
 - Patient function
 - Quality of life

Definition: Optimal Medical Therapy

- Treatment of contributing comorbidities
- Standard lifestyle modifications including dietary interventions
- Optimization of pharmacotherapy
- Appropriate use of other devices such as implantable cardiac resynchronization devices, cardioverter-defibrillators, or pacemakers

Discussion Questions

- a. If there is at least intermediate confidence (mean score ≥ 2.5 in question 1), what prospective patient criteria predict:
 - i. clinically meaningful improvements in health outcomes,
 - ii. equivalent health outcomes, and/or
 - iii. clinically meaningful worsening of health outcomes?

- b. Do these criteria vary if the intended use of the VAD at the time of implantation is:
 - i. bridge-to-transplantation, or
 - ii. destination therapy?

Voting Question 2

How confident are you that there is adequate evidence that one or more facility and/or operator characteristics predict clinically meaningful improvements in health outcomes for patients who receive a VAD in addition to optimal medical therapy compared with optimal medical therapy alone?

Discussion Questions

- a. If there is at least intermediate confidence (mean score ≥ 2.5 in question 2), what facility and/or operator characteristics predict clinically meaningful improvements in health outcomes?
- b. Please discuss the role, if any, of facility VAD specific certification to assure attainment and maintenance of any characteristics identified in question 2a.
- c. Please discuss the role, if any, of the heart team concept in the management of patients who receive a VAD.

Definition: Heart Team Concept

- Cohesive, multi-disciplinary team of medical professionals
- Embodies collaboration and dedication across medical specialties to offer optimal patient-centered care

Voting Question 3

How confident are you that these conclusions are generalizable to the Medicare beneficiary population?

Discussion Question

Which conclusions are likely or unlikely to be generalizable to the Medicare beneficiary population?

Voting Question 4

How confident are you that clinically significant evidentiary gaps remain regarding the use of VADs?

Discussion Question

If there is at least intermediate confidence (mean score ≥ 2.5 in question 4), please discuss any significant gaps identified and how CMS might support their closure.