Ventricular Assist Devices and Total Artificial Hearts

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

"A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed." *(Medicare NCD 20.9.1)*

There are three kinds of ventricular assist devices: biventricular (BiVADs), right ventricular (RVAD), and left ventricular (LVADs). Also available are percutaneous Ventricular Assist Devices (pVADS), or circulatory assist devices, and intra-aortic balloon pump (IABP) devices (also known as aortic counterpulsation devices).

Total artificial hearts (TAH)s may be implanted temporarily as a bridge to heart transplantation, or permanently as destination therapy for those who are not candidates for transplantation.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: See the FDA Regulatory Status chart below for examples of various devices.

CMS Coverage Manuals*	For ***implantable aortic counterpulsation ventricular assist systems (Category III CPT codes 0451T-0463T)*** Medicare Benefit Policy Manual Chapter 14 – Medical Devices *See Section 10 in the following link:* §10 - Coverage of Medical Devices While U.S. Food and Drug Administration (FDA) approval does not guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, any device that has not received FDA-approval would not be considered medically reasonable or necessary, including implantable aortic counterpulsation ventricular assist systems.
National Coverage Determinations (NCDs)*	For ***VADs*** *(e.g., BiVAD, RVAD, LVAD. For percutaneous VADs [pVADs], see next row. For implantable aortic counterpulsation ventricular assist systems, see above)*: ✓ Ventricular Assist Devices (20.9.1) For Medicare-approved VAD destination therapy facilities, see CMS Website.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	For ***insertion of pVADs (CPT codes 33990,33991, and 33995)***: ✓ Percutaneous Endovascular Cardiac Assist Procedures and Devices RETIRED: A52967 **Scroll to the "Public Version(s)" section at the bottom of the Article for links to prior versions if necessary.
Medical Policy Manual	*Medicare coverage guidance is not available for artificial hearts. Therefore, the health plan's medical policy is applicable.* ✓ Ventricular Assist Devices and Total Artificial Hearts, Surgery, Policy No. 52 *(see "NOTE" below)*

NOTE: According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- History and Physical documenting indications for procedure and device;
- Type of therapy (bridge-to-transplant [BTT], destination therapy [DT], or post-cardiotomy for VADs);
- For artificial hearts: The names of the device and Coverage with Evidence Development (CED) study;
- For VADs: Name of device to be used, date of open heart surgery (if applicable), facility where the procedure will be performed, documentation of stage of chronic heart failure, failed optimal medical management, left ventricular ejection fraction (LVEF), and documentation of demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min (see NCD for exceptions to this requirement).

REGULATORY STATUS

Medicare coverage for medical devices and products includes those approved by the FDA through the pre-market approval (PMA) process or the 510(k) process, FDA-approved IDE Category B devices, and hospital institutional review board (IRB) approved IDE devices, and only when used within the context of the FDA-approved clinical trial.[4] Note, the fact a service or procedure has been FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

Intra-aortic balloon pump (IABP) devices have been developed as a treatment for cardiogenic shock. IABPs consist of a helium-filled balloon placed in the aorta that deflates during cardiac systole to increase forward blood flow. The inflation and deflation of the balloon is computer-controlled and can be regulated by either a pressure-sensing catheter or an electrocardiogram. These devices have not been FDA approved, and therefore the evidence for these devices is not reviewed in detail.

DEVICE	DEVICE TYPE	MANUFACTURER	FDA APPROVAL	INDICATION
HeartMate II®	LVAD	Thoratec Corp.	PMA	Bridge to transplant and destination therapy

DEVICE	DEVICE TYPE	MANUFACTURER	FDA APPROVAL	INDICATION
Thoratec® IVAD	BiVAD	Thoratec Corp.	PMA + Supplement	Bridge to transplant and post-cardiotomy
Levitronix Centrimag®	RVAD	Levitronix, LLC	HDE	Postcardiotomy (temporary circulatory support for up to 14 days)
Novacor®	LVAD	World Heart, Inc.	PMA	Bridge to transplant
DeBakey VAD® Child	LVAD	MicroMed Technology, Inc.	HDE	Bridge to transplant in children 5-16 years of age
EXCOR® Pediatric System	BiVAD	Berlin Heart, Inc.	HDE	Bridge to transplant, pediatric (newborns to teens)
Jarvik 2000	LVAD	Jarvik Heart, Inc.	IDE[5]	
HeartWare® Ventricular Assist System (HVAD®)	VAD	Heartware Intl., Inc.	PMA	Bridge to transplant – for use in-hospital or out-of-hospital
Impella® Recover LP 2.5	pVAD	Abiomed, Inc.	510(k)	Partial circulatory support using an extracorporeal bypass control unit for periods up to 6 hours
TandemHeart®	pVAD	CardiacAssist, Inc.	510(k)	Temporary left ventricular bypass of six hours of less
AutoCat 2 WAVE® IABP System	IABP	Arrow Intl., Inc.	None	
Maquet CS300™ IABP	IABP	Maquet Cardiovascular, LLC	None	
SynCardia Temporary TAH (formerly called CardioWest™)	Temporary TAH	SynCardia Systems, Inc.	510(k)	Bridge to transplant – for use inside the hospital
AbioCor® TAH	Permanent TAH	AbioMed, Inc.	HDE	Destination therapy

CROSS REFERENCES

Extracorporeal Membrane Oxygenation (ECMO) for the Treatment of Cardiac and Respiratory Failure in Adults, Medicine, Policy No. M-152

Surgical Ventricular Restoration, Surgery, Policy No. M-149

Heart Transplants, Transplant, Policy No. M-02

Heart-Lung Transplants, Transplant, Policy No. M-03

REFERENCES

1. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §320 - Artificial Hearts and Related Devices
2. Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies
3. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §320.3 – Ventricular Assist Devices (VADs)
4. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 – Coverage of Medical Devices
5. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §20.1 - Medicare Requirements for Coverage of Items and Services in FDA-approved Category A and B IDE Studies

CODING

NOTE: There is no specific code for reporting prolonged extracorporeal percutaneous transseptal ventricular assist device; the appropriate code for reporting this procedure is 33999.

Codes	Number	Description
CPT	33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
	33928	Removal and replacement of total replacement heart system (artificial heart)
	33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
	33975	Insertion of ventricular assist device; extracorporeal, single ventricle
	33976	Insertion of ventricular assist device; extracorporeal, biventricular
	33977	Removal of ventricular assist device; extracorporeal, single ventricle
	33978	Removal of ventricular assist device; extracorporeal, biventricular
	33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
	33980	Removal of ventricular assist device, implantable intracorporeal, single ventricular
	33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
	33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
	33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass

	33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
	33991	; left heart, both arterial and venous access, with transseptal puncture
	33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
	33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
	33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
	33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion
	33999	Unlisted procedure, cardiac surgery
HCPCS	Q0477-Q0509	Ventricular assist device accessories, code range
	L8698	Miscellaneous component, supply or accessory for use with total artificial heart system

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*