Regence Oregon and Utah | Regence Idaho and select counties of Washington

Medicare Advantage Policy Manual **Policy ID:** M-SUR52

Ventricular Assist Devices and Total Artificial Hearts

Published: 01/01/2019

Next Review: 12/2019

Last Review: 12/2018 ***Medicare Link(s) Revised:*** *02/01/2019*

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. IABP devices were developed as a treatment for cardiogenic shock. They 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; however, these devices have not been FDA approved.

"An artificial heart is a biventricular replacement device which requires removal of a substantial part of the native heart, including both ventricles..." *(NCD 20.9)*

TAHs 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*	None
National Coverage Determinations (NCDs)*	For ***artificial hearts (aka, Total Artificial Hearts, or TAH)***: ✓ Artificial Hearts and Related Devices (20.9) For Medicare-approved artificial heart bridge-to-transplant (BTT) and destination therapy (DT) CED studies, see CMS Website. **Note:** If the procedure is rendered as part of a Category A IDE study, the device itself is non-covered.[2] For ***VADs*** *(e.g., BiVAD, RVAD, LVAD. For percutaneous VADs [pVADs] and implantable aortic counterpulsation ventricular assist systems, see next row)*: ✓ 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 (LCAs)*	For ***insertion of pVADs (CPT codes 33990 and 33991)***: ✓ Percutaneous Endovascular Cardiac Assist Procedures and Devices (A52967) For ***implantable aortic counterpulsation ventricular assist systems (Category III CPT codes 0451T-0463T)***: ✓ Non-Covered Services (L35008) **Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.

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. *(Noridian LCD L35008)* 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).

DEVICE	DEVICE TYPE	MANUFACTURER	FDA APPROVAL	INDICATION
HeartMate II®	LVAD	Thoratec Corp.	PMA	Bridge to transplant and destination therapy
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; arterial access only
	33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
	33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion
	33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion
	33999	Unlisted procedure, cardiac surgery
	0451T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and

		programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)
	0452T	; aortic counterpulsation device and vascular hemostatic seal
	0453T	; mechano-electrical skin interface
	0454T	; subcutaneous electrode
	0455T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes)
	0456T	; aortic counterpulsation device and vascular hemostatic seal
	0457T	; mechano-electrical skin interface
	0458T	; subcutaneous electrode
	0459T	Relocation of skin pocket with replacement of implanted aortic counterpulsation ventricular assist device, mechano- electrical skin interface and electrodes
	0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode
	0461T	; aortic counterpulsation device
	0462T	Programming device evaluation (in person) with iterative adjustment of the implantable mechano-electrical skin interface and/or external driver to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable aortic counterpulsation ventricular assist system, per day
	0463T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic counterpulsation ventricular assist system, per day
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.*