MEDICAL COVERAGE POLICY	
SERVICE:	**Ventricular Assist Devices (VAD) and Artificial Heart**
Policy Number:	**201**
Effective Date:	**07/01/2020**
Last Review:	**05/28/2020**
Next Review Date:	**05/28/2021**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Ventricular Assist Devices and Artificial Heart

Also Known as: Left Ventricular Assist Devices, Percutaneous Left Ventricular Assist Devices, Right Ventricular Assist Devices, Total Artificial Heart

PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

SWHP/FC may consider a TAC-approved (see below) and FDA-approved **ventricular assist device** (VAD) medically necessary for 1 or more of the following FDA-approved indications:

- Post-cardiotomy. 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; **OR**
- As a bridge to transplant for members who are not expected to survive until transplantation AND are awaiting heart transplantation as evidenced by listing on the waitlist of the Organ Procurement and Transplantation Network (see exclusions below); **OR**
- As destination therapy when all of the following criteria are met:
    - The device has received FDA approval for a destination therapy indication; **AND**
    - Member has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is NOT a candidate for heart transplant; **AND**
    - Member has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or has been balloon pump dependent for 7 days, or has been IV inotrope dependent for 14 days; **AND**

- Has a left ventricular ejection fraction (LVEF) less than 25%; **AND**
- Has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min (Note: This criterion may be waived in persons who are unable to perform exercise stress testing).

SWHP/FC may consider **total artificial hearts** (TAH) medically necessary as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options and 1 or more of the following:

- Are currently listed as heart transplantation candidates; OR
- Are undergoing evaluation for heart transplantation and are not expected to survive until a donor heart can be obtained.

Percutaneous ventricular assist devices (pVADs) that are FDA approved may be considered medically necessary for 1 or more of the following FDA approved indications:

- Impella® - partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours; OR
- TandemHeart® - temporary left ventricular bypass of 6 hours or less.

SWHP/FC may consider FDA-approved **right ventricular assist devices (RVADs)**; e.g., the CentriMag Right Ventricular Assist System) medically necessary for temporary circulatory support when all of the following criteria are met:

- RVAD is used for up to 30 days for members in cardiogenic shock due to acute right ventricular failure; AND
- Member is willing and able to be treated with an anticoagulant

SWHP/FC may consider FDA approved **pediatric ventricular assist devices** medically necessary when ALL of the following are met:

- Child has documented end-stage left ventricular failure
- An age appropriate VAD will be used until a donor heart can be obtained

Current FDA-approved pediatric VADs include the Berlin Heart EXCOR Pediatric Ventricular Assist Device (forchildren aged 16 years or younger) and the HeartAssist 5 Pediatric Ventricular Assist Device (for children aged 5 to 16 years). The EXCOR Pediatric VAD can be used in children up to 60 kg body weight. The HeartAssist 5 Pediatric VAD can be used in children with a BSA greater than or equal to 0.7 m2 and less than 1.5 m2).

Exclusions:

SWHP/FC does **NOT** consider a VAD for any other reason as medically necessary and is considered experimental, investigational or unproven.

Xenotransplantion/heterotransplantation (a graft transplantation between different species) of a baboon heart OR porcine/swine (pig) heart is considered experimental, investigational and/or unproven as bridge to transplantation.

OVERVIEW:

VADs may be useful for short-term (days), intermediate (weeks) and long-term (months to years) use. Short-term assisted circulation is used to facilitate the performance of complex coronary interventional procedures and as a bridge to recovery in postcardiotomy patients who cannot be weaned off cardiopulmonary bypass, individuals in cardiogenic shock, patients with low cardiac output after cardiac surgery and individuals with acute rejection after heart transplant.

Devices for intermediate and long-term use are implanted as intracorporeal devices and are commonly used as a bridge to transplantation (BTT), a bridge to recovery (BTR) when heart transplantation is not indicated and it is anticipated that the individual may recover, and as destination therapy (individuals who are inappropriate for heart transplant and in whom no return to adequate cardiac functioning is expected).

In general, VADs may facilitate myocardial recovery for individuals with reversible ventricular dysfunction, temporarily maintain circulation until transplant, or extend the length and quality of life in the terminally ill.

MANDATES:

There are no mandated benefits or regulatory requirements for SWHP/FC to provide coverage for these services.

SUPPORTING DATA:

Medical Exclusions:

Contraindications for bridge to transplant LVADs include conditions that would generally exclude patients for heart transplant, such as chronic irreversible hepatic, renal, or respiratory failure, morbid obesity (BMI >35), life expectancy (in the absence of cardiovascular disease) less than 2 years, systemic infection (including HIV), and malignancies or blood dyscrasia. Due to potential problems with adequate function of the VAD, implantation is also contraindicated in patients with uncorrected valvular disease.

Contraindications to heart transplant:

1. New York Heart Association (NYHA) classification of heart failure I or II (see below),
2. Member does not have potential for conditioning and rehabilitation after transplant (i.e., member is moribund or morbidly obese);
3. Life expectancy (in the absence of cardiovascular disease) is less than 2 years;
4. Presence of malignancy (except for non-melanomatous skin cancers);
5. Inadequate pulmonary, liver and renal function;
6. Active infections that are not effectively treated, including HIV infection;
7. Presence of active or recurrent pancreatitis;
8. Diabetes with severe end-organ damage (neuropathy, nephropathy with declining renal function and proliferative retinopathy);
9. Uncontrolled and/or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen; and

10. Active alcohol or chemical dependency that interferes with compliance to a strict treatment regimen.

Technical Assessment: TAC group approved:
(Intrathoracic only)
Impella 2.5 (Not 5.0)
Heartmate II/ Thoratec
TandemHeart (intrathoracic)

New York Heart Association (NYHA) Functional Classification of Heart Failure
NYHA Class Symptoms

I. No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
II. Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
III. Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.
IV. Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Source: New York Heart Association, 1994.

CODES:

CPT Codes:	33927 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 ventricle 33981 Replacement of extracorporeal ventricular assist device, single or biventricular, 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 33991 Insertion of ventricular assist device, percutaneous 33992 Removal of percutaneous ventricular assist device at separate and distinct session from insertion 33993 Repositioning of percutaneous ventricular assist device with imaging guidance

	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 92970 Cardioassist-method of circulatory assist; internal 93750 Interrogation of ventricular assist device (VAD)
CPT Not Covered:	
HCPCS codes:	Q0478 Q0479 Q0480 Q0481 Q0482 Q0483 Q0484 Q0485 Q0486 Q0487 Q0488 Q0489 Q0490 Q0491 Q0492 Q0493 Q0494 Q0495 Q0496 Q0497 Q0498 Q0499 Q0500 Q0501 Q0502 Q0503 Q0504 Q0505 Q0506
ICD10:	I11.0 Hypertensive Heart Disease with CHF I13.x Hypertensive Heart and Renal Disease with CHF I20 - I25 Ischemic Heart Diseases I42.x Cardiomyopathy 143.x Cardiomyopathy in other diseases 144.x Atrioventricular and left bundle branch block 145.x Other conduction disorders 148 Atrial fibrillation and flutter R57.0 Cardiogenic Shock

CMS: NCD: Ventricular Assist Device (20.9.1) effective date – 10/30/2013.
There is no LCD**.** CMS published a decision memorandum liberalizing criteria for coverage of ventricular assist devices (CMS, 2010). The CMS policy removes body size criteria and eases restrictions around the required duration of failed medical therapy and peak oxygen consumption. Under the rule changes, CMS will reimburse ventricular assist devices as destination therapy when all of the following criteria are met:

1. The device to be implanted has received FDA approval for a destination therapy indication; and
2. Patient has NYHA Class IV end-stage ventricular heart failure and is not suitable for heart transplantation; and
3. Patient has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days (down from 60 of the prior 90 days in the earlier criteria), or patient has been balloon pump dependent for seven days, or patient has been IV inotrope dependent for 14 days; and
4. Patient has a left ventricular ejection fraction (LVEF) less than 25%; and
5. Patient has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min (increased from 12 ml/kg/min in the previous criteria).

CMS policy: CAG-00162N (BTT) and CAG-00119R2 (DT)

POLICY HISTORY:

Status	Date	Action
New	03/12/2012	New policy
Reviewed	02/14/2013	Reviewed.
Reviewed	05/30/2013	CMS reference added. ICD10 codes added.
Reviewed	05/22/2014	No changes
Reviewed	09/25/2014	Minor update to criteria based on updated NCD
Reviewed	05/28/2015	No changes
Reviewed	07/07/2016	Added FDA information and pediatric exclusion
Reviewed	06/13/2017	Expanded CMS information
Reviewed	01/16/2018	Added coverage criteria for artificial heart. Updated other criteria
Reviewed	01/08/2019	Minor corrections
Updated	01/23/2020	Added criteria for percutaneous VAD and right heart VAD
Updated	05/28/2020	Reviewed and aligned for FirstCare and SWHP

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Bank AJ, Mir SH, Nguyen DQ, et al. Effects of left ventricular assist devices on outcomes in patients undergoing heart transplantation. Ann Thorac Surg. 2000;69(5):1369-1374.
2. Wessex Institute for Health Research and Development, Development and Evaluation Committee. Left ventricular assist devices (LVADs) for end stage heart failure. Development and Evaluation Committee Report; 103. Southampton, UK: Wessex Institute; 1999.
3. Magovern GJ, Park SB, Maher TD. Use of a centrifugal pump without anticoagulants for postoperative left ventricular assist. World J Surg. 1985;9:25-36.
4. Pennington DG, McBride LR, Swartz MT, et al. Use of the Pierce-Donachy ventricular assist device in patients with cardiogenic shock after cardiac operation. Ann Thorac Surg. 1989;47:130-135.
5. Abou-Awdi NL, Frazier OH. The HeartMate: A left ventricular assist device as a bridge to cardiac transplantation. Transplant Proc. 1992;24(5):2002-2003.
6. Cheng A, Trivedi JR, Van Berkel VH, Massey, Slaughter. Comparison of total artificial heart and biventricular assist device support as bridge-transplantation. J Card Surg. 2016 Oct;31(10):648-653
7. Nguyen A, Pozzi M, Mastroianni C, Léger P, Loisance D, Pavie A, Leprince P, Kirsch M. Bridge to transplantation using paracorporeal biventricular assist devices or the Syncardia temporary total artificial heart: is there a difference? J Cardiovasc Surg (Torino). 2015 Jun;56(3):493-502.