MEDICAL COVERAGE POLICY

SERVICE: Ventricular Assist Devices (VAD) and Artificial Heart

Policy Number:	**201**
Effective Date:	**07/1/2024**
Last Review:	**06/10/2024**
Next Review:	**06/10/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

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.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). NCD 20.9.1 Ventricular Assist Devices. Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

Criteria set forth in NCD 20.9.1
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:

A. Have New York Heart Association (NYHA) Class IV heart failure; and
B. Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
C. 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.

Medicare also has explicit rules regarding the multidisciplinary team managing members with these devices. Please refer to the NCD.

For Medicare coverage of other devices please refer to Medicare documents.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

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

A. 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**
B. 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**
C. As destination therapy when all of the following criteria are met:
    1. The device has received FDA approval for a destination therapy indication; **AND**
    2. Member has New York Heart Association (NYHA) Glass IV end-stage ventricular heart failure and is NOT a candidate for heart transplant; **AND**
    3. Member has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (AGE) 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**
    4. Has a left ventricular ejection fraction (LVEF) less than 25%; **AND**
    5. 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).

BSWHP 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:

A. Are currently listed as heart transplantation candidates; OR
B. 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:

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

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

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

BSWHP may consider FDA approved pediatric ventricular assist devices medically necessary when ALL of the following are met:

A. Child has documented end-stage left ventricular failure
B. 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 (for children 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:

A. BSWHP does **NOT** consider a VAD for any other reason as medically necessary and is considered experimental, investigational or unproven.
B. 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.

BACKGROUND:

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.

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

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.

MANDATES: None

CODES:
Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes	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 33995 - Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only 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 Codes Not Covered	
HCPCS Codes	Q0478 - Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type Q0479 - Power module for use with electric or electric/pneumatic ventricular assist device, replacement only Q0480 - Driver for use with pneumatic ventricular assist device, replacement only Q0481 - Microprocessor control unit for use with electric ventricular assist device, replacement only Q0482 - Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only Q0483 - Monitor/display module for use with electric ventricular assist device, replacement only Q0484 - Monitor/display module for use with electric or electric/pneumatic ventricular assist

	device, replacement only Q0485 - Monitor control cable for use with electric ventricular assist device, replacement only Q0486 - Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only Q0487 - Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only Q0488 - Power pack base for use with electric ventricular assist device, replacement only Q0489 - Power pack base for use with electric/pneumatic ventricular assist device, replacement only Q0490 - Emergency power source for use with electric ventricular assist device, replacement only Q0491 - Emergency power source for use with electric/pneumatic ventricular assist device, replacement only Q0492 - Emergency power supply cable for use with electric ventricular assist device, replacement only Q0493 - Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only Q0494 - Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only Q0495 - Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only Q0496 - Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only Q0497 - Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only Q0498 - Holster for use with electric or electric/pneumatic ventricular assist device, replacement only Q0499 - Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only Q0500 - Filters for use with electric or electric/pneumatic ventricular assist device, replacement only Q0501 - Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only Q0502 - Mobility cart for pneumatic ventricular assist device, replacement only Q0503 - Battery for pneumatic ventricular assist device, replacement only, each Q0504 - Power adapter for pneumatic ventricular assist device, replacement only, vehicle type Q0505 - Miscellaneous supply or accessory for use with ventricular assist device Q0506 - Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only Q0507 - Miscellaneous supply or accessory for use with an external ventricular assist device Q0508 - Miscellaneous supply or accessory for use with an implanted ventricular assist device Q0509 - Miscellaneous supply or accessory for use with an implanted ventricular assist device
ICD-10 Codes	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

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
Reviewed	05/27/2021	Added coverage for 33995 (rt hrt VAD). Added reference to new NCD effective 7/27/21.
Reviewed	05/26/2022	Clarified Medicare coverage
Reviewed	05/25/2023	Removed confusing information in non-criteria section
Reviewed	06/10/2024	Formatting changes, added hyperlinks to CMS and TMPPM resources, beginning and ending note sections updated to align with CMS requirements and business entity changes.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP 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 BSWHP 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.

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.