Department of Origin: Integrated Healthcare Services	**Effective Date:** 09/13/22
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 09/13/22
Clinical Policy Document: Ventricular Assist Devices (VAD) and Total Artificial Heart (TAH)	**Replaces Effective Clinical Policy Dated:** 06/10/22
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PURPOSE:
The intent of this clinical policy is to ensure care is medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I or II

I. Ventricular assist devices (VAD) – must satisfy the following: A or B, and none of C

A. Initial Request - any of the following: 1-3
1. Bridge to recovery – all of the following: a and b
a. Member has a potentially reversible condition (eg, cardiogenic shock, cardiomyopathy, myocarditis, following cardiac surgery when the patient cannot be weaned from cardiopulmonary bypass [post-cardiotomy]); and
b. Device is being used according to the FDA-approved labeling instructions.

2. Bridge to transplant – either of the following: a or b
a. Adults - both of the following: 1) and 2)
1) Approved for or are undergoing evaluation for heart transplantation; and
2) Device is being used according to the FDA-approved labeling instructions.
b. Children – both of the following: 1) and 2)
1) Approved for or are undergoing evaluation for heart transplantation due to left ventricular/biventricular dysfunction; and
2) Device is being used according to the FDA-approved labeling instructions – either of the following: a) or b0
a) Berlin Heart EXCOR Pediatric Left or Biventricular Assist Device for children aged 16 years or younger – must satisfy one of the following: i or ii
i. Left ventricular support – member has severe *New York Heart Association (NYHA) Class IV* (or Ross Functional Class IV for subjects equal to or less than 6 years of age) heart failure refractory to optimal medical therapy; or
ii. Biventricular support – member has cardiomyopathy, repaired structural heart disease (eg, anomalous left coronary artery from the pulmonary artery [ALCAPA], aortic stenosis) or acquired heart disease (eg, myocarditis, Kawasaki disease).
b) HeartAssist 5 Pediatric Left Ventricular Assist Device for children aged 5 to 16 years – member has *NYHA Class IV* end-stage heart failure refractory to medical therapy.

3. Destination therapy for adults - all of the following: a - e
   a. Not a candidate for heart transplantation; and
   b. Device is being used according to the FDA-approved labeling instructions; and
   c. *NYHA Class IV* end-stage ventricular heart failure; and
   d. Demonstrates any of the following: 1) – 3)
      1) Failure to respond to optimal medical management for at least 60 days; or
      2) Failure to respond to a trial of intraaortic balloon pump (IABP) management; or
      3) IV inotrope dependent for 14 days.
   e. Left ventricular ejection fraction (LVEF) less than 25%.

[Note: Although the HeartWare Ventricular Assist Device is only approved as a bridge to transplant, due to its small size, it may also be considered medically necessary as *destination therapy* when required due to the member's anatomy, where criteria for destination therapy are met and its use for the member is not part of a clinical trial.]

B. Replacement/upgrade – Member currently has an axial (eg, HeartMate II [HMII]) or centrifugal continuous-flow (hVAD) pump with evidence of pump thrombosis – requesting upgrade to a magnetically levitated centrifugal continuous-flow pump (eg, HeartMate 3) that is FDA-approved for the requested indication.

C. Contraindications - none of the following: 1 - 8
   1. Heart failure that can be reasonably expected to recover without mechanical circulatory support (ie, VAD); or

   2. Major comorbid illness that is anticipated to limit survival to < 2 years - such as any of the following: a - d
      a. An advanced malignancy
      b. Severe and irreversible hepatic disease, ie, cirrhosis not expected to improve with long term mechanical circulatory support (ie, VAD)
      c. Severe lung disease (including pulmonary arterial hypertension that is not related to chronic heart failure, not World Health Organization group II)
      d. Severe neurological or neuromuscular disorder

   3. Acute valvular infective endocarditis with bacteremia; or

   4. Detailed neurocognitive evaluation is advised in patients with cognitive impairment to ascertain ability to comprehend and manage the VAD; or

   5. History of non-adherence with demonstrated inability to comply with medical recommendations on multiple occasions that has not been successfully remediate; or

   6. Active and uncontrolled alcohol and substance abuse; or

   7. Neuromuscular disease that severely compromises the ability to use and care for external system components or to ambulate and exercise; or

   8. Current pregnancy.

II. Total Artificial Heart, temporary (Syncardia TAH-t) – must satisfy: A, and none of B

A. All of the following: 1 - 3
   1. Device is used as a bridge to transplantation; and
   2. Approved for or is undergoing evaluation for heart transplantation; and
   3. At risk of imminent death from biventricular failure

B. Contraindications – none of the following: 1 - 2
   1. Insufficient space in chest area
   2. Cannot be adequately anticoagulated on the TAH-t

   [Note: If VAD or TAH-t approved, send referral to reinsurance/stop loss.]

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

Artificial heart for destination therapy (permanent), totally implantable is considered investigative (see Investigative List)

DEFINITIONS:
Bridge to Recovery:
A mechanical circulatory device used short-term (usually up to 2 weeks) to support a patient with a potentially reversible cardiac condition

Bridge to Transplant:
A ventricular assist device or total artificial heart is used to maintain cardiac function while the patient waits for a heart transplant

Destination Therapy:
A ventricular assist device is used to sustain life when the patient is not a candidate for a heart transplant, and there is no plan for a heart transplant

Dyscrasia:
An imbalance in blood components

New York Heart Association (NYHA) Classification:
- Class I: patients with no limitation of activities; they suffer no symptoms from ordinary activities.
- Class II: patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion.
- Class III: patients with marked limitation of activity; they are comfortable only at rest.
- Class IV: patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest.

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Ventricular Assist Device (VAD):
A mechanical pump that's used to support heart function and blood flow in people who have weakened hearts. The device takes blood from a lower chamber of the heart and helps pump it to the body and vital organs, just as a healthy heart would.

BACKGROUND:
The U.S. Food and Drug Administration (FDA) approved devices include, but may not be limited to, the following:

- Ventricular Assist Devices
  - Bridge to recovery (short-term): AbioMed AB5000, AbioMed BVS5000, Centrimag RVAD, Thoratec IVAD, Thoratec VAD System, HeartMate 3 LVAD, HeartWare HVAD, and Percutaneous VADs (eg, TandemHeart, Impella Recover LP 2.5, Impella CP Heart Pump, Impella Recover LP 5.0, Impella RP, HeartMate PHP
  - Bridge to transplant: AbioMed AB5000, HeartMate II, HeartMate 3, HeartMate IP, HeartMate SNAP VE LVAS, HeartMate VE LVAS, HeartMate XVE LVAS, HeartWare VAS, Thoratec IVAD, Thoratec VAD System
  - Bridge to transplant (pediatric): EXCOR Pediatric VAD, HeartAssist 5 Pediatric VAD (formerly known as DeBakey VAD Child)
  - Destination therapy: AbioMed BVS5000, HeartMate II, HeartMate 3, HeartMate SNAP VE LVAS, HeartWare HVAD
- Total Artificial Heart - temporary (TAH-t): Syncardia

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Prior Authorization: Yes, per network provider agreement.
Precertification: Yes

CODING:
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)
33975 Insertion of ventricular assist device; extracorporeal, single ventricle
33976 Insertion of ventricular assist device; extracorporeal, biventricular
33979 Insertion of ventricular assist device; implantable intracorporeal, single ventricle
33981 Replacement of extracorporeal ventricular assist device, single or biventricular pump(s), single or each pump
33982 Replacement of ventricular assist device pump(s), single or biventricular pump(s), 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 Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33995 Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

REFERENCES:
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2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MP/H008 FDA-Approved Humanitarian Use Devices
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Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

We will:

- Provide free aids and services to people with disabilities to communicate effectively with us, such as:
    - Qualified sign language interpreters
    - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provide free language services to people whose primary language is not English, such as:
    - Qualified interpreters
    - Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

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Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

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Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY: 1.866.631.8597).