Ventricular assist devices (VADs) and total artificial hearts

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is required for insertion of an implantable ventricular assist device (VAD).

Prior authorization is required for placement of a total artificial heart (TAH).

Prior authorization is not required if either of the devices listed above is used under emergency circumstances for a critically ill member in an in-patient setting. Emergency use is defined as necessary to save the life or protect the immediate well-being of a given patient. However, services with specific coverage criteria may be reviewed concurrently or retrospectively to determine medical necessity.

Prior authorization is not required for the replacement or removal of a ventricular assist device (VAD) or total artificial heart (TAH).

Prior authorization is not required for percutaneous ventricular assist devices (pVADs).

Coverage

Insertion of an implantable ventricular assist device (VAD) or total artificial heart (TAH) is covered per the member’s plan documents when the criteria outlined below are met and the procedure is performed at a HealthPartners Transplant Center of Excellence. Please see the Related Content section for the Transplant Centers of Excellence documents.

Indications that are covered

Implantable ventricular assist device

Adult

1. An implantable VAD is covered as a bridge to recovery in patients with a potentially reversible condition when the following criteria are met:
   A. The requested device has received approval from the Food and Drug Administration (FDA) and is being used in accordance with device-specific, FDA-approved indications.
   B. The patient is in acute cardiogenic shock from which recovery is expected or the patient is unable to be weaned from cardiopulmonary bypass following heart surgery.

2. An implantable VAD is covered as a bridge to transplant when the following criteria are met:
   A. The requested device has received approval from the Food and Drug Administration (FDA) and is being used in accordance with device-specific, FDA-approved indications.
   B. The patient is undergoing evaluation to determine candidacy for heart transplantation; or
   C. The patient is currently listed as a heart transplantation candidate at a HealthPartners Transplant Center of Excellence and is not expected to survive until a donor heart can be obtained.

3. An implantable VAD is covered as destination therapy when the following criteria are met:
   A. The patient is not a candidate for a heart transplant
   B. The requested device has received approval from the Food and Drug Administration (FDA) and is being used in accordance with device-specific, FDA-approved indications.
   C. There is documentation of New York Heart Association (NYHA) Class IV end-stage left ventricular heart failure for at least 90 days; and
      i. Class IV heart failure symptoms have failed to respond to optimal medical management, including medication management as clinically appropriate for the patient, for at least 45 of the last 60 days; or the patient has been dependent on a temporary mechanical circulatory support device, such as an intra-aortic balloon pump (IABP), for at least 7 days, or IV inotrope dependent for 14 days; and
      ii. The left ventricular ejection fraction (LVEF) is less than 25%; and
      iii. There are demonstrated functional limitations with a peak oxygen consumption measurement not required if balloon-pump dependent or physically unable to perform the test.
1. A pediatric (EXCOR®, HeartAssist 5®) implantable VAD is covered as a bridge to transplant in children when all of the following criteria are met:
   A. The requested device has received approval from the Food and Drug Administration (FDA) and is being used in accordance with the device-specific, FDA-approved indications.
   B. There is documentation of NYHA Class IV, end-stage heart failure/end-stage left ventricular failure; and
   C. The patient is currently undergoing evaluation to determine candidacy for heart transplantation or is listed as a cardiac transplant candidate at a HealthPartners Transplant Center of Excellence.

Percutaneous ventricular assist device

1. FDA approved pVADs are considered medically necessary when utilized for the following indications:
   A. Short term circulatory support for treatment of cardiogenic shock; or
   B. Short term circulatory support during urgent high risk percutaneous coronary intervention

Total artificial heart

Adult

1. A Total artificial heart (TAH) is covered as a bridge to transplant when the following criteria are met:
   A. The requested device has received approval from the Food and Drug Administration (FDA) and is being used in accordance with the device-specific, FDA-approved indications.
   B. There is documentation of biventricular heart failure that has failed to respond to optimal medical therapy.
   C. The patient is not expected to survive until a donor heart can be obtained.
   D. The patient is listed as a candidate for heart transplant at a HealthPartners Transplant Center of Excellence.

2. All other applications of total artificial hearts, including but not limited to, the use of total artificial heart as destination therapy because their use for a non-approved indication is investigative.

Pediatric

1. A total artificial heart (TAH) is covered as a bridge to transplant when the following criteria are met:
   A. The patient is at risk of imminent death from non-reversible biventricular failure or inoperable complex congenital cardiac conditions.
   B. The patient may either be undergoing evaluation to determine candidacy for heart transplantation or is listed as a heart transplant candidate at a HealthPartners Transplant Center of Excellence.

2. All other applications of total artificial hearts, including but not limited to, the use of total artificial heart as destination therapy because their use for a non-approved indication is investigative.

<table>
<thead>
<tr>
<th>FDA Approved Ventricular Assist Devices and Total Artificial Hearts</th>
<th>FDA approved indications, including approved Humanitarian Device Exemptions (HDE)</th>
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<tbody>
<tr>
<td>HeartMate II®</td>
<td>Left ventricular device. Bridge to transplant or recovery; destination therapy</td>
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<td>HeartMate 3™</td>
<td>Left ventricular device Bridge to transplant or recovery; destination therapy. Adult and pediatric patients.</td>
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<td>CentriMag™Circulatory Support System</td>
<td>Left, right or biventricular use for bridge to recovery when unable to be weaned after open heart surgery; for bridge to recovery for right-sided heart failure due to cardiogenic shock</td>
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<tr>
<td>EXCOR® VAD</td>
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<tr>
<td>HeartAssist 5® VAD</td>
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<td>SynCardia TAH</td>
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Definitions

Ventricle is one of a pair of muscular chambers of the heart that pumps blood throughout the body.

Ventricular assist device (VAD) describes any of a variety of mechanical pumps that are used to replace the function of either the right, left, or both ventricles to assist a damaged or weakened heart to pump blood.

Percutaneous ventricular assist devices (pVAD) were introduced as an alternative to the intra-aortic balloon pump
(IABP) in individuals with cardiogenic shock following acute myocardial infarction (heart attack). They are intended for short term use in members who require acute circulatory support.

**Total artificial heart (TAH)** is an implantable support device that serves as a total replacement for both ventricles of a failing heart. The ventricles and valves are surgically removed, and the device is sewn to the remaining atria (top half of the heart). The TAH replaces the function of the two ventricles and four valves of the heart to pump blood to the lungs and systemic circulatory system.

**Adult** is defined as age 18 years old and above.

**Pediatric** is defined as below the age of 18 years old.

**Bridge to recovery** refers to short term (usually one day to two weeks) use of mechanical circulatory support in a patient with a potentially reversible cardiac condition.

**Bridge to transplant** refers to the use of a mechanical support device while the patient is awaiting a heart transplant.

**Destination therapy** refers to permanent support for a member with irreversible heart failure who is not a candidate for heart transplantation.

**Heart failure** is a chronic, progressive disease in which the heart muscle weakens and cannot pump enough blood to sustain the body systems. Vital organs like the kidneys, liver and brain are starved of the oxygen and nutrients they need in order to function properly. Heart failure often develops after the heart has been damaged or weakened by other conditions, including coronary artery disease, heart attack, high blood pressure and cardiomyopathy.

**New York Heart Association (NYHA) classification**: The most commonly used classification system of heart failure. It places the individual in one of four categories based on degree of limitation during physical activity, using the limitations/symptoms related to degrees of breathing difficulty, shortness of breath, and/or angina pain.

- Class I (Mild) - No limitation of physical activity.
- Class II (Mild) - Slight limitation of physical activity.
- Class III (Moderate) - Marked limitation of physical activity; comfortable at rest, but less than ordinary physical activity results in symptoms of heart failure such as fatigue, rapid/irregular heartbeat or shortness of breath.
- Class IV (Severe) - Inability to carry on any physical activity without discomfort. Symptoms of heart failure are present at rest.

**End stage heart failure** refers to the most severe stage of heart failure in which both sides of the heart are failing to pump enough blood to sustain the body.

**Codes**

*If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.*

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### Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-983-7979 or 1-800-233-9645.

Approved: Medical Director Committee 5/8/95; Revised 12/9/03, 11/22/10; 09/12/2013, 9/2014, 9/2015, 9/2016, 12/5/2023

#### References

3. Birks, EJ, Treatment of advanced heart failure with a durable mechanical circulatory support device: UptoDate, Hunt (Ed), UpToDate, Waltham, MA (Accessed October 20, 2023)  