TITLE: MECHANICAL CIRCULATORY SUPPORT DEVICES

EFFECTIVE DATE: June 1, 2017

This policy was developed with input from specialists in cardiology and cardiovascular surgery, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY
These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of mechanical circulatory support devices. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions
A. Biventricular heart failure is when both sides of the heart are failing to pump enough blood to sustain the body.
B. Bridge to transplant is the use of a mechanical support device while the patient is awaiting a heart transplant.
C. Cardiac resynchronization therapy (CRT) or biventricular pacing is the use of a biventricular pacemaker, in individuals with heart failure, which sends electrical impulses to both ventricles of the heart to help them beat together in a more synchronized pattern to improve cardiac function.
D. Destination therapy is the use of a mechanical support device for long-term, permanent support in a patient who is not a candidate for a heart transplant.
E. Heart failure is a condition that causes the muscle in the heart wall to slowly weaken and enlarge, preventing the heart from pumping enough blood, carrying oxygen and nutrients, to meet the body’s needs. Symptoms of heart failure include shortness of breath, fatigue, and fluid retention.
F. Humanitarian Device Exemption (HDE) is designated by the FDA’s Center for Devices and Radiological Health (CDRH). An HDE authorizes marketing of a Humanitarian Use Device (HUD) although the effectiveness of the device for the specific indication has not been demonstrated. A HUD must meet the following criteria: it must be used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States per year; the device would not be available to a person with such a disease or condition unless the exemption is granted; no comparable device (other than a device that has been granted such an exemption) is available to treat or diagnose the disease or condition; the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. HUDs are subject to individual review because they are exempt from the effectiveness data required by the FDA to gain approval.
G. New York Heart Association (NYHA) functional classification is 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. The classification is:

1. NYHA Class I: Cardiac disease, but no symptoms and no limitation in ordinary physical activity (e.g. shortness of breath when walking, climbing stairs, etc.)
2. NYHA Class II: Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity
3. NYHA Class 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.
4. NYHA Class IV: Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

H. **Total artificial heart (TAH)** is an implantable biventricular support device that serves as a total replacement for both ventricles of the failing heart. The ventricles and valves are surgically excised 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 by pumping blood to both the pulmonary and systemic circulation. The TAH provides circulatory support while waiting for a donor heart and may also restore kidney and liver function due to improved blood flow. The TAH is connected to two lines that exit through the skin and connect to a large power generating console, which operates and monitors the device, while the patient is hospitalized. A portable power generating device (SynCardia Freedom® Driver System) is also available which allows the patient to leave the hospital. Currently there is only one FDA approved device, SynCardia temporary Total Artificial Heart (TAH-t).

I. A **Ventricular Assist Device (VAD)** describes any of a variety of mechanical blood pumps that are used singularly to replace the function of either the right, left or both ventricles.

1. A VAD may be appropriate in, but not limited to, the following situations:
   a. To support patients who have had open heart surgery and cannot be weaned from cardiopulmonary bypass
   b. To support patients after an acute myocardial infarction. Ventricular assistance after cardiotomy or a heart attack is usually short term (one day to two weeks)
   c. To support patients awaiting a heart transplant (bridge to transplant)
   d. To support patients in persistent/severe cardiogenic shock from any etiology.

2. Device selection is based on specific FDA-labeled indications:
   a. Heartware® Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular failure. It is designed for in-hospital and out-of-hospital settings.
   b. Thoratec(R) Ventricular Assist Device (VAD) System is intended as a bridge to cardiac transplantation for use in patients suffering from end-stage heart failure who are candidates for cardiac transplantation, at imminent risk of dying before donor heart procurement, and dependent on, or have incomplete response to, continued vasopressor support.
   c. Thoratec HeartMate II® Left Ventricular Assist System (LVAS) is indicated for use as a bridge to transplant in cardiac transplant patients at risk of imminent death from non-reversible left ventricular failure. It is designed for in-hospital and out-of-hospital settings.
   d. Impella Recover® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit for periods of up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.
   e. TandemHeart® PTVA® System is intended for extracorporeal circulatory support using an extracorporeal bypass circuit for periods appropriate to cardiopulmonary bypass, up to six hours.
   f. Levitronix Centrimag® Right Ventricular Assist System (RVAS) has FDA status as a Humanitarian Use Exemption (HDE) device and is indicated for temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure.
   g. Berlin Heart EXCOR® Pediatric Ventricular Assist Device. This device is a HDE intended to provide mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients. Pediatric candidates with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support may be treated using the EXCOR.
   h. HeartAssist 5® Pediatric VAD, formerly called the DeBakey VAD Child Left Ventricular Assist System is a HDE intended for both home and hospital use in children who are between 5 and 16 years old, and have end-stage left ventricular failure requiring temporary mechanical blood
II. Comments
   A. Heart transplant is the definitive therapy for advanced and refractory heart failure. This, however, is challenged by an inadequate supply of donor hearts, finite graft survival, and complications of immunosuppressive therapy that accompanies heart transplantation. The development of durable and safe ventricular assist devices and total artificial heart has allowed mechanical circulatory support to emerge as an effective form of therapy.
   B. SynCardia temporary Total Artificial Heart (TAH-t) is currently the only FDA approved device.
   C. TAH is generally reserved for individuals with end-stage heart failure/disease when there are no other alternative treatments.

<table>
<thead>
<tr>
<th>MEDICAL NECESSITY CRITERIA</th>
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<tbody>
<tr>
<td>VENTRICULAR ASSIST DEVICES (VADs)</td>
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<tr>
<td>I. Indications for bridge to transplant</td>
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<tr>
<td>Bridge to transplant is considered medically necessary when documentation in the medical records indicates that all of the following are met:</td>
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<tr>
<td>A. The device is approved by the U.S. Food and Drug Administration (FDA)</td>
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<tr>
<td>B. The individual is approved and listed as a candidate for a heart transplant</td>
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<tr>
<td>C. The individual is not expected to survive until a donor heart can be obtained</td>
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<tr>
<td>D. The individual does not have an active malignancy with a life expectancy of less than two years</td>
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<tr>
<td>E. No documented contraindications present as indicated by all of the following:</td>
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<tr>
<td>1. No acute valvular infectious endocarditis with active bacteremia</td>
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<tr>
<td>2. No active infection of an implantable cardioverter defibrillator (ICD) or pacemaker with bacteremia</td>
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<tr>
<td>3. No irreversible multiorgan failure</td>
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<tr>
<td>4. No neuromuscular disease that severely compromises the ability to use and care for external system components, or to ambulate and exercise</td>
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<tr>
<td>5. Not currently pregnant</td>
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<tr>
<td>6. No inability to physically operate the pump, respond to device alarms, report signs and symptoms of device malfunction or other health care needs to the health care team</td>
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<tr>
<td>7. No active psychiatric illness that requires long-term institutionalization or inability to care for or maintain device</td>
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<tr>
<td>8. No demonstrated inability to comply with medical recommendations on multiple occasions</td>
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<td>9. No active substance abuse, including alcohol</td>
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<td>10. No confirmed cirrhosis or an increased Model for End Stage Liver Disease (MELD) score.</td>
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<td>II. Indications for destination therapy</td>
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<td>Destination therapy is considered medically necessary when documentation in the medical records indicates that all of the following are met:</td>
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<td>A. The device is approved by the FDA</td>
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<tr>
<td>B. The individual has been evaluated and determined not to be eligible for a heart transplant</td>
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<tr>
<td>C. There is documented Class IV New York Heart Association (NYHA) end stage left ventricular heart failure</td>
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<tr>
<td>D. The individual has received optimal medical management (i.e., medication, intra-aortic balloon pump, oxygen) for at least 60 of the last 90 days, or survival is in jeopardy</td>
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<tr>
<td>E. There is a life expectancy of less than two years</td>
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<td>F. The individual is not on permanent dialysis</td>
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<tr>
<td>G. The individual does not have an active malignancy with a life expectancy of less than two years.</td>
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<tr>
<td>H. No documented contraindications present as indicated by all of the following:</td>
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<tr>
<td>1. No acute valvular infectious endocarditis with active bacteremia</td>
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<tr>
<td>2. No active infection of an implantable cardioverter defibrillator (ICD) or pacemaker with bacteremia</td>
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<tr>
<td>3. No irreversible multiorgan failure</td>
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<td>4. No neuromuscular disease that severely compromises the ability to use and care for external system components, or to ambulate and exercise</td>
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<tr>
<td>5. Not currently pregnant</td>
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<tr>
<td>6. No inability to physically operate the pump, respond to device alarms, report signs and symptoms of device malfunction or other health care needs to the health care team</td>
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<tr>
<td>7. No active psychiatric illness that requires long-term institutionalization or inability to care for or maintain device</td>
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III. Indications for bridge to recovery

Bridge to recovery is considered medically necessary when documentation in the medical records indicates that all of the following are met:

A. The device has been approved by the FDA

B. One of the following must be met:
   1. The individual has a diagnosis of acute cardiogenic shock or acute myocarditis
   2. Following cardiac surgery for patients who cannot be weaned from cardiopulmonary bypass.

C. No documented contraindications present as indicated by all of the following:
   1. No acute valvular infectious endocarditis with active bacteremia
   2. No active infection of an implantable cardioverter defibrillator (ICD) or pacemaker with bacteremia
   3. No irreversible multiorgan failure
   4. No neuromuscular disease that severely compromises the ability to use and care for external system components, or to ambulate and exercise
   5. Not currently pregnant
   6. No inability to physically operate the pump, respond to device alarms, report signs and symptoms of device malfunction or other health care needs to the health care team
   7. No active psychiatric illness that requires long-term institutionalization or inability to care for or maintain device
   8. No demonstrated inability to comply with medical recommendations on multiple occasions
   9. No active substance abuse, including alcohol
   10. No confirmed cirrhosis or an increased Model for End Stage Liver Disease (MELD) score.

IV. Indications for pediatric bridge to transplant

The FDA has granted a humanitarian device exemption (HDE) for pediatric devices. Medica considers an FDA-approved humanitarian device exemption (HDE) device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.

TOTAL ARTIFICIAL HEART (TAH)

I. Indications for total artificial heart

Total artificial heart is considered medically necessary when documentation in the medical records indicates that all of the following criteria are met:

A. The total artificial heart device is approved by the FDA (currently there is only one FDA approved device, SynCardia temporary Total Artificial Heart (TAH-t))

B. Diagnosis of biventricular heart failure

C. The individual is approved and listed as a candidate for a heart transplant (device used as a bridge to transplant)

D. The individual has failed optimal medical therapy

E. The individual is not expected to survive until a donor heart can be obtained

F. No documented contraindications present as indicated by all of the following:
   1. No acute valvular infectious endocarditis with active bacteremia
   2. No active infection of an implantable cardioverter defibrillator (ICD) or pacemaker with bacteremia
   3. No irreversible multiorgan failure
   4. No neuromuscular disease that severely compromises the ability to use and care for external system components, or to ambulate and exercise
   5. Not currently pregnant
   6. No inability to physically operate the pump, respond to device alarms, report signs and symptoms of device malfunction or other health care needs to the health care team
   7. No active psychiatric illness that requires long-term institutionalization or inability to care for or maintain device
   8. No demonstrated inability to comply with medical recommendations on multiple occasions
9. No active substance abuse, including alcohol
10. No confirmed cirrhosis or an increased Model for End Stage Liver Disease (MELD) score.

COVERAGE ISSUES
1. Prior authorization is required for mechanical circulatory support devices.
2. Coverage may vary according to the terms of the member's plan document.
3. Medica considers an FDA-approved humanitarian device exemption (HDE) device (e.g., AbioCor® Implantable Replacement Heart, the Berlin Heart EXCOR® Pediatric Ventricular Assist Device, Levitronix Centrimag®, or the HeartAssist® Pediatric VAD) medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm. Accessed February 8, 2017.
4. The use of non-FDA-approved devices and/or their use for non-approved indications is investigative and therefore, not covered.
5. For Medicare members, refer to the following, as applicable:
   • Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9). http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=artificial+heart&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAABAAA AAAAA%3d%3d&. Accessed December 30, 2016.
   • Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NC%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&KeyWord=ventricular+assist&KeyWordLookUp=Title&KeyWordSearchType=Exact&kg=true&bc=IAAAABAAAAAAA%3d%3d&. Accessed December 30, 2016.
6. Refer to Medica’s Utilization Management Policy, Heart Transplantation (Adult and Pediatric).
7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.
8. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

DOCUMENT HISTORY
<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>June 2014</th>
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<tbody>
<tr>
<td>MPC Endorsement Date(s)</td>
<td>02/2015, 04/2016, 02/2017</td>
</tr>
<tr>
<td>Administrative Updates</td>
<td>05/01/2017</td>
</tr>
</tbody>
</table>

References:

**Pre-04/2016 MPC:**


8. ECR Institute. Health Technology Forecast: *total Artificial Heart (Temporary) with Portable Driver as Bridge to Heart Transplantation*. October 2014. Plymouth, Meeting, PA.


02/2016 MTAC review for Ventricular Assist Devices (VADs):


04/2016 MPC:

No new references

02/2017 MPC:

34. Food and Drug Administration (FDA). Listing of CDRH Humanitarian Device Exemptions.  