Coverage:

Cardiac Mechanical Assist Devices may be eligible for coverage as a bridge to a heart transplant for a patient who is currently a heart transplant candidate. The devices must have FDA approval. When used as a bridge to heart transplantation, the implantation of a cardiac mechanical assist device is considered the first step in the heart transplant process.

Cardiac Mechanical Assist Devices are considered investigational and are not eligible for coverage for the following:

- A bridge to coronary disease recovery,
- Permanent heart replacement or alternative to transplantation, or
- Permanent circulatory assistance.

Xenotransplantation/heterotransplantation (a graft transplantation between different species) of a baboon heart OR porcine/swine (pig) heart is not eligible for coverage as it is considered investigational as a bridge to heart transplantation.

Description:

Cardiac Mechanical Assist Devices are used primarily as circulatory support for those patients with a failing heart who are awaiting heart transplantation (known as a "bridge to heart transplantation"). These devices have been successfully used to treat cardiogenic shock. Cardiogenic shock is shock resulting from decline in cardiac output (pumping function) secondary to:

- serious heart disease (usually myocardial infarction or heart attack, severe cardiomyopathy, or mechanical obstruction or compression of the heart) OR

- following cardiac surgery (the post cardiotomy period).

A number of mechanical devices are now available. They can be classified as internal or external, electronically or pneumatically powered.

Left Ventricular Assist Devices (LVADs, LAVS, or VADs) are surgically implanted into the patient (frequently into the abdomen) and provide the pumping action that the patient's own heart can no longer provide. The pumping action is provided by an external component that is either pneumatically or electronically driven. These devices may not be well suited for post cardiotomy use, as they are designed for left ventricular cannulation only and require removal of a portion of ventricular tissue at the point of insertion.

In 1998, the FDA approved two devices, the HeartMate and the Novacor.
These are used as bridging devices for patients with irreversible heart failure who are, also, heart transplant candidates whose condition is deteriorating so rapidly they are likely to die within 24 to 48 hours. Both devices are pneumatically driven. These devices allow patients to leave the hospital while awaiting heart transplant. The longest "bridging time" from insertion of this device to a successful heart transplant has been 48 weeks.

Prior to 1998, the FDA approved bridge to transplantation devices required inpatient monitoring while the patient awaits heart transplantation. These devices are the following:

- Thoratec in 1995, that can supply either left ventricular support alone or biventricular support (both the right and left ventricles),
- Pneumatic HeartMate in 1994, as a left ventricular support, and
- Abiomed BVS 5000 in 1992, that primarily supports patients in the post-cardiotomy setting.

Intra-aortic balloon pumps (IABP) have been used to support blood pressure. The IABP is inserted through an artery of the groin and is programmed to inflate and deflate in conjunction with the pumping and resting of the heart. IABPs have been used as a "bridge to heart transplantation" and as a method of stabilization until cardiac surgery can repair a mechanical lesion and revascularize the heart.

Centrifugal ventricular support devices (such as the BioMedicus Pump) have been used as a support for post-cardiotomy cardiac failure, cardiac allograft failure, bridge to heart transplantation, resuscitation, and post emergent percutaneous transluminal coronary angioplasty.

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RATIONAL:

Because of the limited supply of donor hearts, prospective recipients continue to die while on the waiting list for heart transplantation. Use of long-term support devices, such as a bridge to transplantation, may reduce this mortality. However, bridging strategies cannot alleviate the human organ donor shortage.

For long-term, permanent mechanical circulatory support for coronary disease or recovery, continued investigation and clinical evaluation are required.

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PRICING:

A centrifugal ventricular support device (such as the Bio-Medicus Pump) is considered part of the surgical charges, and should not be billed separately.

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DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical
technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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