Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Category: Surgery
***Current Policy Effective Date: 3/1/12**

Title: Cardiac Support Devices

****Procedure Code(s): 33999**

Description/Background

Heart failure is a progressive and debilitating disease subsequent to left ventricular remodeling characterized by dilatation and progressive dysfunction of the left ventricle. A variety of conditions, including myocardial infarctions, valvular disorders, uncontrolled high blood pressure and other cardiovascular abnormalities may cause heart failure.

The heart's natural response to impaired function is to work harder in order to pump blood. The excessive workload on the heart stresses the muscle walls and damages the muscular structure, eventually resulting in an unhealthy enlargement of the heart. In the body's continuous attempt to supply the body with adequate blood, the stress on the heart continues to build in a degenerative cycle of muscle damage, which eventually results in end-stage heart failure or death.

There is currently no known cure for heart failure; however, drug therapy is currently the standard of care to alleviate symptoms and slow its progression. Although many advances have been made over the past decade, drugs as well as other therapies have not demonstrated long-term effectiveness in preventing or reversing the disease.

Currently cardiac support devices are being investigated, specifically designed to alleviate the increased pressure against the muscle wall and the left ventricular remodeling. One such device attempts to pull the left ventricular walls together to change its shape from a sphere to an open figure eight. The other consists of a proprietary mesh wrap that is placed around the entire heart to provide gentle, permanent support while allowing normal cardiac function. At the present time, these devices have not been approved by the US Food and Drug Administration (FDA).

*See policy history boxes for any previous effective dates if applicable
**See section "CPT/HCPCS Level II Codes" for additional code(s) if applicable.

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

33999

Diagnoses / Medical Conditions

- Dilated cardiomyopathy
- Heart failure

Medical Policy Statement

Cardiac support devices are considered experimental and investigational. The safety and effectiveness of these devices have not been scientifically demonstrated and they have not received approval from the United States Food and Drug Administration (FDA).

Rationale

The randomized controlled trials comparing cardiac support devices to other drug, surgical or medical therapies do not permit scientific assessment of the efficacy of their use. The clinical trials were limited in the number of patients and the selection criteria. Additionally, the long-term outcomes of the risks of the implantation of these devices and the impact of implantation on future heart procedures are not available

Medical Policy Position Summary (Non-clinical summary statement for customer use)

Heart failure is the result of the heart's inability to provide enough blood flow to the body. It results in changes to the heart and may be caused by many different conditions (e.g., heart attacks, valve disorders and uncontrolled high blood pressure). It is estimated that more than five million people in the United States suffer from this weakening condition.

To date, there is no known cure for heart failure; however, drug therapy is currently the standard of care to lessen symptoms and slow the progress of heart failure. Although, many advances have been made over the past decade, drugs, as well as other therapies, have not demonstrated long-term effectiveness in preventing or reversing the disease.

Cardiac support devices are being investigated to improve the functional capacity and well-being of heart failure patients. One of the devices attempts to reshape the left ventricle and the other consists of a mesh wrap that is placed around the entire heart to provide gentle, permanent support. These are the first therapies designed to address ventricular wall stress

in order to prevent and reverse the progression of damage caused by heart failure. These cardiac support devices are intended to improve the heart's structure and function, leading to improvements in the quality of a patient's life.

The FDA has not approved these devices and there is insufficient evidence to support their use, therefore, they are considered experimental and investigational.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

Related Policies

N/A

Medicare Information

There is currently no national or local Medicare policy addressing this specific service.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Acker, M., "Mitral valve surgery in heart failure: Insights from the Acorn Clinical Trial," *The Journal of Thoracic and Cardiovascular Surgery,* Vol. 132, No. 3, September 2006, pp. 568-577.
- Blom, A., et al., "Cardiac Support Device Modified Left Ventricular Geometry and Myocardial Structure after Myocardial Infarction," *Circulation*, Vol. 112, August 30, 2005, pp. 1274-1283.
- Eschenhagen, T. and Zimmerman, W., "Engineering Myocardial Infarction," *Circulation Research*, Vol. 97, December 2005, pp. 1220–1231.
- *Hayes Outlook*, "CorCap™ Cardiac Support Device (CSD)," Lansdale, PA: HAYES, Inc., December 1, 2004, Archived June 23, 2005.
- Labrousse, L., "Parachute-like Technique for Off-Pump Implantation of Cardiac Support Device in Isolated and Combined Procedure," *European Journal of Cardio-Thoracic Surgery*, Vol. 32, No. 5, November 2007, pp. 807-809.

- Livi, U., et al., “One-year clinical experience with the Acorn CorCap™ cardiac support device: results of a limited market release safety study in Italy and Sweden,” *Italian Heart Journal*, Vol. 6, January 2005, pp. 59-65.
- Mann, D., et al., “Clinical evaluation of the CorCap Cardiac Support Device in Patients with Dilated Cardiomyopathy,” *Annals of Thoracic Surgery*, Vol. 84, No. 4, October 2007, pp. 1226-1235.
- Raman, J., MMed, FRACS, et al., “Ventricular Constraint in Severe Heart Failure Halts Decline in Cardiovascular Function Associated with Experimental Dilated Cardiomyopathy,” *Annals of Thoracic Surgery*, Vol. 76, No. 1, January 2003, pp. 141-147.
- Starling, R., et al., “Sustained Benefits of the CorCap Cardiac Support Device on Left Ventricular Remodeling: Three Year Follow-Up Results from the Acorn Clinical Trial,” *Annals of Thoracic Surgery*, Vol. 84, No. 4, October 2007, pp. 1236-1242.
- United States Food and Drug Administration (FDA), *Centers for Devices and Radiological Health,* “Summary of the Medical Device Dispute Resolution Panel Meeting,” December 15, 2006, www.fda.gov/cdrh/panelsummary/dispute121506.html.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 9/30/11, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/07	5/14/07	6/5/07	Joint policy established.
7/1/08	5/17/08	5/18/08	Routine maintenance
7/1/09	4/21/09	5/11/09	Routine maintenance
3/1/12	12/13/11	12/21/11	Routine maintenance

Next Review Date: 4th Qtr, 2012

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CARDIAC SUPPORT DEVICES

I. Short Description:

Heart failure is the result of the heart's inability to provide enough blood flow to the body. It results in changes to the heart and may be caused by many different conditions (e.g. heart attacks, valve disorders, uncontrolled high blood pressure). It is estimated that more then five million people in the United States suffer from this weakening condition.

To date, there is no known cure for heart failure; however, drug therapy is currently the standard of care to lessen symptoms and slow the progress of heart failure. Although many advances have been made over the past decade, drugs, as well as other therapies, have not demonstrated long-term effectiveness in preventing or reversing the disease.

Cardiac support devices are being investigated to improve the functional capacity and well- being of heart failure patients. One of the devices attempts to reshape the left ventricle and the other consists of a mesh wrap that is placed around the entire heart to provide gentle, permanent support. These are the first therapies designed to address ventricular wall stress in order to prevent and reverse the progression of damage caused by heart failure. These cardiac support devices are intended to improve the heart's structure and function, leading to improvements in the quality of a patient's life.

The FDA has not approved these devices and there is insufficient evidence to support their use, therefore, they are considered investigational.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Not Covered
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service
BlueCaid	Not Covered

III. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.

- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.

IV. Effective Dates:

Policy updated: 7/1/08, 7/1/09, 3/1/12
JUMP policy effective date: 7/1/07