

Corporate Medical Policy

Surgical Ventricular Restoration

File Name:	surgical_ventricular_restoration
Origination:	6/2010
Last CAP Review:	6/2011
Next CAP Review:	6/2012
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Description of Procedure or Service

Surgical ventricular restoration (SVR) is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in patients with akinetic segments of the heart, secondary to either dilated cardiomyopathy or post-infarction left ventricular aneurysm. The SVR procedure is usually performed after coronary artery bypass grafting (CABG) and may proceed or be followed by mitral valve repair or replacement and other procedures such as endocardectomy and cryoablation for treatment of ventricular tachycardia. A key difference between surgical ventricular restoration and ventriculectomy (i.e., for aneurysm removal) is that in SVR, the ventricle is reconstructed using patches of autologous or artificial material that are placed to close the defect while maintaining the desired ventricular volume and contour. In addition, SVR is distinct from partial left ventriculectomy (i.e., the Batista procedure, see policy titled “Partial Left Ventriculectomy”), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

The SVR procedure may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER), or the Dor procedure after Vincent Dor, MD. Dr. Dor pioneered the expansion of techniques for ventricular reconstruction and is credited with treating congestive heart failure patients with SVR in conjunction with CABG.

The CorRestore™ Patch System is a device approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process that is specifically labeled for use “as an intracardiac patch for cardiac reconstruction and repair.” The device consists of an oval tissue patch made from glutaraldehyde-fixed bovine pericardium. It is identical to other marketed bovine pericardial patches except that it incorporates an integral suture bolster in the shape of a ring that is used along with ventricular sizing devices to restore the normal ventricular contour.

Please note: For Partial Left Ventriculectomy see BCBSNC Evidenced Based Guideline titled “Partial Left Ventriculectomy”.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Surgical ventricular restoration is considered investigational for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm.

Benefits Application

Surgical Ventricular Restoration

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Surgical Ventricular Restoration is covered

Not Applicable

When Surgical Ventricular Restoration is not covered

Surgical ventricular restoration is considered investigational for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm. BCBSNC does not cover investigational services.

Policy Guidelines

Surgical Ventricular Restoration is a procedure that removes akinetic areas of the left ventricular of patients with ischemic cardiomyopathy. A number of uncontrolled studies have suggested that surgical ventricular restoration can improve the hemodynamic functioning in selected patients with ischemic cardiomyopathy. However, the pivotal RCT, the STICH trial, did not report any improvements in clinical outcomes or quality of life measures for patients undergoing SVR in addition to standard CABG surgery. As a result of this data, the impact of SVR on net health outcome remains uncertain.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 33548

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 1/14/2010

U.S. Food and Drug Administration. 501(K) Summary for CorRestore™ Patch System Retrieved on 03/19/04 from http://www.accessdata.fda.gov/cdrh_docs/pdf4/k040162.pdf

Jones RH, Velazquez EJ, Michler RE, et al; the STICH Hypothesis 2 Investigators. Coronary bypass surgery with or without surgical ventricular reconstruction. *N Engl J Med.* 2009;360(17):1705-1717

Senior Medical Director review 5/2010

Specialty Matched Consultant Advisory Panel review 6/2010

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National Institutes of Health (NIH). Clinical Trial #NCT00023595. Comparison of Surgical and Medical Treatment for Congestive Heart Failure and Coronary Artery Disease (STICH). Retrieved on May 26, 2011 from

<http://clinicaltrials.gov/ct2/show/NCT00023595?term=NCT00023595&rank=1>

Specialty Matched Consultant Advisory Panel review 6/2011

Marchenko A, Chernyavsky A, Efendiev V et al. Results of coronary artery bypass grafting alone and combined with surgical ventricular reconstruction for ischemic heart failure. *Interact Cardiovasc Thorac Surg* 2011; 13(1):46-51. Retrieved on September 9, 2011 from

<http://icvts.ctsnetjournals.org/cgi/content/full/13/1/46>

Mark DB, Knight JD, Velazquez EJ et al. Quality of life and economic outcomes with surgical ventricular reconstruction in ischemic heart failure: results from the Surgical Treatment for Ischemic Heart Failure trial. *Am Heart J* 2009; 157(5):837-44, 44 e1-3. Retrieved on September 9, 2011 from <http://www.nejm.org/doi/full/10.1056/NEJMoa0805151>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 8/11/11

Policy Implementation/Update Information

6/8/2010 New policy developed. Surgical ventricular restoration is considered investigational for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm. Senior Medical Director review 5/3/10. Specialty Matched Consultant Advisory Panel review 6/2010. Notification given 6/8/10 for effective date of 9/14/10.(mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. References updated. Policy Guidelines updated. (mco)

9/30/11 Policy guidelines updated. References updated. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.