

Corporate Medical Policy

Surgical Ventricular Restoration

File Name: surgical_ventricular_restoration
Origination: 6/2010
Last Review: 6/2023

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 ischemic dilated cardiomyopathy.

The SVR procedure is usually performed after coronary artery bypass grafting (CABG) and may precede 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 SVR and ventriculectomy (i.e., for aneurysm removal) is that in SVR, circular “purse string” suturing is used around the border of the aneurysmal scar tissue. Tightening of this suture is believed to isolate the akinetic or dyskinetic scar, bring the healthy portion of the ventricular walls together, and restore a more normal ventricular contour. If the defect is large (i.e., an opening >3 cm), the ventricle may also be reconstructed using patches of autologous or artificial material to maintain the desired ventricular volume and contour during closure of the ventriculotomy. In addition, SVR is distinct from partial left ventriculectomy, which does not attempt to specifically resect akinetic segments and restore ventricular contour.

The SVR procedure is also known as surgical anterior ventricular endocardial restoration (SAVER), left ventricular reconstructive surgery, endoventricular circular plasty, or the Dor procedure, named after the surgeon who pioneered the expansion of techniques for ventricular reconstruction and is credited with treating congestive heart failure patients with SVR in conjunction with CABG.

Regulatory Status

The U.S. Food and Drug Administration regulates the marketing of devices used as intracardiac patches through the 510(k) clearance process. These devices are Class II and are identified as apolypropylene, polyethylene terephthalate, or polytetrafluoroethylene patch or pledget placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures. Biological tissue may also be a component of the patches. In 2004, the CorRestore™ Patch System (Somanetics; acquired by Medtronic) was cleared for marketing by the U.S. Food and Drug Administration (FDA) 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.

In 2020, Ancora Heart announced that it received an FDA investigational device exemption for its AccuCinch® ventricular restoration system. This exemption allows Ancora Heart to proceed with an initial efficacy and safety study in patients with heart failure and reduced ejection fraction.

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*****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. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

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. BCBSNC does not cover investigational services.

Policy Guidelines

The evidence for use of surgical ventricular restoration (SVR) in patients with ischemic dilated cardiomyopathy as an adjunct to CABG surgery, includes a large randomized controlled trial (RCT) (another RCT reported results, but most of the trial enrollees overlapped with those in the larger trial) and uncontrolled studies. Relevant outcomes are overall survival, symptoms, quality of life, hospitalizations, resource utilization, and treatment-related morbidity. The RCT, the Surgical Treatment of Ischemic Heart Failure trial, did not report significant improvements in quality of life outcomes for patients undergoing SVR as an adjunct to standard coronary artery bypass grafting (CABG) surgery. Several uncontrolled studies have suggested that SVR can improve hemodynamic functioning in selected patients with ischemic cardiomyopathy; however, these studies are considered lower quality evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

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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

National Institutes of Health (NIH). Clinical Trial #NCT00023595. Comparison of Surgical and Medical Treatment for Congestive Heart Failure and Coronary Artery Disease (STICH). Last reviewed May 18, 2012, 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

Specialty Matched Consultant Advisory Panel review 6/2012

Wijns W, Kolh P, Danchin N et al. Guidelines on myocardial revascularization. Eur Heart J 2010; 31(20):2501-55. Retrieved from <http://eurheartj.oxfordjournals.org/content/31/20/2501.long>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 8/9/12

Specialty Matched Consultant Advisory Panel review 6/2013

Medical Director review 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 8/8/13

Specialty Matched Consultant Advisory Panel review 6/2014

Medical Director review 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 8/14/14

Specialty Matched Consultant Advisory Panel review 6/2015

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Medical Director review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 8/13/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 2/11/16

Specialty Matched Consultant Advisory Panel review 6/2016

Medical Director review 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 2/2017

Medical Director review 2/2017

Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017

Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 3/2019

Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 3/2020

Specialty Matched Consultant Advisory Panel review 6/2020

Medical Director review 6/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.103, 3/2021

Specialty Matched Consultant Advisory Panel review 6/2021

Medical Director review 6/2021

Specialty Matched Consultant Advisory Panel review 6/2022

Medical Director review 6/2022

Specialty Matched Consultant Advisory Panel review 6/2023

Medical Director review 6/2023

Policy Implementation/Update Information

6/8/10 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)

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- 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)
- 7/10/12 Specialty Matched Consultant Advisory Panel review 6/2012. No changes to Policy Statement. (mco)
- 10/16/12 References updated. No changes in Policy Statements. (mco)
- 7/16/13 Specialty Matched Consultant Advisory Panel review 6/2013. Medical Director review. Description section updated. References updated. (mco)
- 10/1/13 References updated. No changes in Policy Statements. (mco)
- 7/15/14 Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review 6/2014. No changes to Policy Statements. (mco)
- 10/28/14 References updated. Policy Guidelines section updated. No changes to Policy Statements. (td)
- 10/1/15 Specialty Matched Consultant Advisory Panel review 6/2015. Medical Director review 6/2015. Policy Guidelines section updated. References updated. Policy Statements remain unchanged. (td)
- 4/1/16 Description section updated. References updated. (td)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/2016. Medical Director review 6/2016. (jd)
- 3/31/17 Minor edits, deleted “or post infarction left ventricular aneurysm” from policy statement. No change to policy intent. References updated. Medical Director review, 2/2017. (jd)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/2017. (jd)
- 7/27/18 Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)
- 7/1/19 Minor revisions to Regulatory Status section. References update. Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)
- 6/30/20 References updated. Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)
- 7/1/21 Minor update to policy guidelines and references updated. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)
- 7/12/22 Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)
- 6/30/23 Minor update to Description section, References updated. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. (tm)

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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.