Medical Coverage Policy | Surgical Ventricular Restoration



EFFECTIVE DATE: 05 | 01 | 2017

POLICY LAST UPDATED: 04 | 16 | 2019

OVERVIEW

Surgical ventricular restoration (SVR) is 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.

This policy is applicable to Commercial Products only. For BlueCHiP for Medicare, see Related Policies section.

PRIOR AUTHORIZATION

Prior authorization is not required.

POLICY STATEMENT

Commercial Products

Surgical ventricular restoration is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

For BlueCHiP for Medicare, see related policy section for the BlueCHiP for Medicare National and Local Coverage Determinations policy.

MEDICAL CRITERIA

Not applicable

BACKGROUND

Surgical ventricular restoration (SVR) is also known as surgical anterior ventricular endocardial restoration, 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 heart failure patients with SVR and coronary artery bypass grafting.

SVR is usually performed after coronary artery bypass grafting 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 (ie, 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 (ie, 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 (ie, the Batista procedure), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

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 polypropylene, 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 CorRestoreTM Patch System (Somanetics; acquired by Medtronic) was cleared for marketing by the U.S. Food and Drug Administration 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.

For individuals who have ischemic dilated cardiomyopathy who receive SVR as an adjunct to coronary artery bypass grafting, the evidence includes a large randomized controlled trial (another randomized controlled trial reported results, but most trial enrollees overlapped with those in the larger trial) and uncontrolled studies. The relevant outcomes are overall survival, symptoms, quality of life, hospitalizations, resource utilization, and treatment-related morbidity. The randomized controlled trial, 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 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.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

CODING

Commercial Products

The following CPT code is not medically necessary 33548 Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg,ventricular remodeling, SVR, SAVER, Dor procedures)

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations

PUBLISHED

Provider Update, June 2019 Provider Update, June 2018 Provider Update, May 2017

REFERENCES

- 1. Jones RH, Velazquez EJ, Michler RE, et al. Coronary bypass surgery with or without surgical ventricular reconstruction. N Engl J Med. Apr 23 2009;360(17):1705-1717. PMID 19329820
- Holly TA, Bonow RO, Arnold JM, et al. Myocardial viability and impact of surgical ventricular reconstruction on outcomes of patients with severe left ventricular dysfunction undergoing coronary artery bypass surgery: results of the Surgical Treatment for Ischemic Heart Failure trial. J Thorac Cardiovasc Surg. Dec 2014;148(6):2677-2684 e2671. PMID 25152476
- 3. Oh JK, Velazquez EJ, Menicanti L, et al. Influence of baseline left ventricular function on the clinical outcome of surgical ventricular reconstruction in patients with ischaemic cardiomyopathy. Eur Heart J. Jan 2013;34(1):39-47. PMID 22584648
- 4. Michler RE, Rouleau JL, Al-Khalidi HR, et al. Insights from the STICH trial: change in left ventricular size after coronary artery bypass grafting with and without surgical ventricular reconstruction. J Thorac Cardiovasc Surg. Nov 2013;146(5):1139-1145 e1136. PMID 23111018
- 5. Kukulski T, She L, Racine N, et al. Implication of right ventricular dysfunction on long-term outcome in patients with ischemic cardiomyopathy undergoing coronary artery bypass grafting with or without surgical ventricular reconstruction. J Thorac Cardiovasc Surg. May 2015;149(5):1312-1321. PMID 25451487

- 6. Prior DL, Stevens SR, Holly TA, et al. Regional left ventricular function does not predict survival in ischaemic cardiomyopathy after cardiac surgery. Heart. Sep 2017;103(17):1359-1367. PMID 28446548
- 7. 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. May 2009;157(5):837-844, 844 e831-833. PMID 19376309
- 8. 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. Jun 2011;13(1):46-51. PMID 21402600
- 9. Athanasuleas CL, Stanley AW, Buckberg GD, et al. Surgical anterior ventricular endocardial restoration (SAVER) for dilated ischemic cardiomyopathy. Semin Thorac Cardiovasc Surg. Oct 2001;13(4):448-458. PMID 11807740
- Athanasuleas CL, Stanley AW, Jr., Buckberg GD, et al. Surgical anterior ventricular endocardial restoration (SAVER) in the dilated remodeled ventricle after anterior myocardial infarction. RESTORE group. Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the LV. J Am Coll Cardiol. Apr 2001;37(5):1199-1209. PMID 11300423
- 11. Mickleborough LL, Merchant N, Ivanov J, et al. Left ventricular reconstruction: Early and late results. J Thorac Cardiovasc Surg. Jul 2004;128(1):27-37. PMID 15224018
- 12. Bolooki H, DeMarchena E, Mallon SM, et al. Factors affecting late survival after surgical remodeling of left ventricular aneurysms. J Thorac Cardiovasc Surg. Aug 2003;126(2):374-383; discussion 383-375. PMID 12928633
- 13. Sartipy U, Albage A, Lindblom D. The Dor procedure for left ventricular reconstruction. Ten-year clinical experience. Eur J Cardiothorac Surg. Jun 2005;27(6):1005-1010. PMID 15896609
- 14. Hernandez AF, Velazquez EJ, Dullum MK, et al. Contemporary performance of surgical ventricular restoration procedures: data from the Society of Thoracic Surgeons' National Cardiac Database. Am Heart J. Sep 2006;152(3):494-499. PMID 16923420
- 15. Tulner SA, Bax JJ, Bleeker GB, et al. Beneficial hemodynamic and clinical effects of surgical ventricular restoration in patients with ischemic dilated cardiomyopathy. Ann Thorac Surg. Nov 2006;82(5):1721-1727. PMID 17062236
- Tulner SA, Steendijk P, Klautz RJ, et al. Clinical efficacy of surgical heart failure therapy by ventricular restoration and restrictive mitral annuloplasty. J Card Fail. Apr 2007;13(3):178-183. PMID 17448414
- 17. Williams JA, Weiss ES, Patel ND, et al. Outcomes following surgical ventricular restoration for patients with clinically advanced congestive heart failure (New York Heart Association Class IV). J Card Fail. Aug 2007;13(6):431-436. PMID 17675056
- 18. Dzemali O, Risteski P, Bakhtiary F, et al. Surgical left ventricular remodeling leads to better long-term survival and exercise tolerance than coronary artery bypass grafting alone in patients with moderate ischemic cardiomyopathy. J Thorac Cardiovasc Surg. Sep 2009;138(3):663-668. PMID 19698853
- 19. Ohira S, Yamazaki S, Numata S, et al. Ten-year experience of endocardial linear infarct exclusion technique for ischaemic cardiomyopathy. Eur J Cardiothorac Surg. Sep 25 2017. PMID 29029034
- 20. Neumann FJ, Sousa-Uva M, Ahlsson A, et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J. Jan 7 2019;40(2):87-165. PMID 30165437

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENT
This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some case medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constant changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.