

MEDICAL POLICY

SUBJECT: SURGICAL VENTRICULAR RESTORATION	EFFECTIVE DATE: 02/16/06 REVISED DATE: 02/15/07, 02/21/08, 01/15/09, 12/17/09, 12/16/10, 11/17/11 ARCHIVED DATE: 11/15/12 EDITED DATE: 10/17/13, 10/16/14, 10/15/15, 10/20/16, 10/19/17, 10/18/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, surgical ventricular restoration is considered **investigational** for the treatment of ischemic dilated cardiomyopathy or post infarction left ventricular aneurysm.

Refer to Corporate Medical Policy # 7.01.31 regarding Surgical Ventricular Reduction.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Surgical ventricular restoration (SVR) is a procedure designed to treat end-stage heart failure by restoring or remodeling the left ventricle to its normal shape and size in patients with akinetic segments of the heart, secondary to either ischemic dilated cardiomyopathy or post infarction left ventricular aneurysm. The SVR procedure may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER), endoventricular circular patchplasty or the Dor procedure after Vincent Dor, MD. The SVR procedure is usually performed in conjunction with 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.

This policy specifically addresses surgical ventricular restoration, which is different from ventriculectomy. A key difference between surgical ventricular restoration and ventriculectomy (e.g., for aneurysm removal) is that in SVR the ventricle is reconstructed using sutures and or patches of autologous or artificial material that are placed to close the defect while maintaining the desired ventricular volume and contour. Additionally, SVR is distinct from partial left ventriculectomy (e.g., the Bastista procedure) which does not attempt to specifically resect akinetic segments and restore ventricular contour.

RATIONALE:

The CorRestore Patch System is a device FDA approved 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. Chase Medical’s TRISVR Surgical Ventricular Restoration System has also received FDA approval. The kit includes a mannequin endoventricular shaper, TRISVR endoventricular patch and patch sizer.

A review of the peer-reviewed literature revealed many publications on a variety of approaches to surgical ventricular restoration (SVR). These publications consist primarily of case series reports and retrospective review from single centers with the exception of publications from the multi-center RESTORE Group. The RESTORE Group is an international group of cardiologists and surgeons from 13 centers that has investigated SVR in over 1000 patients with ischemic cardiomyopathy following anterior infarction in the past 20 years.

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A five year analysis of 1,198 post-infarction patients in the RESTORE registry (Athanasuleas, et al, 2004) reported an overall 30-day mortality after SVR of 5.3% with ejection fraction (EF) increased from 30% preoperatively to 40% postoperatively and left ventricular end-systolic volume index (LVESVI) decreased from 80 ml/m(2) preoperatively to 56.6 ml/m(2) postoperatively (p less than 0.001). Overall five-year survival was 69%. The study identified EF less than or equal to 30%, LVESVI greater than or equal to 80 ml/m(2), advanced New York Heart Association (NYHA) functional class, and age greater than or equal to 75 years as risk factors for death. Five-year freedom from hospital readmission for CHF was 78%. Preoperatively, 67% of patients were NYHA functional class III or IV and postoperatively, 85% were class I or II.

Studies reviewing SVR for the treatment of post infarction left ventricular aneurysm reported that no benefit could be demonstrated when linear closure was compared with ventricular patch reconstruction for left ventricular aneurysm repair.

While the SVR procedure has been performed for many years, the available data is inadequate to permit conclusions regarding health benefits associated with SVR. Specifically, the lack of any randomized controlled trials comparing SVR to other surgical or medical therapies does not permit scientific assessment of the efficacy of SVR. Additionally, patient selection criteria and optimal surgical techniques are still undetermined.

A multi-center prospective, randomized trial, Surgical Treatment of Ischemic Heart Failure (STICH), was initiated in 2002 and will randomize patients to receive medical therapy alone, medical therapy with CABG, or medical therapy with CABG and endoventricular circular patchplasty. The STICH trial is sponsored by the NIH and expects to enroll 2,800 patients (at 50 clinical sites) with heart failure, left ventricular ejection fraction less than 35% and coronary artery disease amenable to CABG. It is hoped that the results of this trial will demonstrate the impact of coronary revascularization combined with endoventricular patchplasty on cardiac function and long-term survival. RH Jones, et al (2009) published outcomes (median follow-up 48 months) of 1000 patients enrolled in the STICH trial. Surgical ventricular reconstruction reduced the end-systolic volume index by 19%, as compared with a reduction of 6% with CABG alone. Cardiac symptoms and exercise tolerance improved from baseline to a similar degree in the two study groups. However, no significant difference was observed in the primary outcome (composite of death from any cause, hospitalization from cardiac causes), which occurred in 292 patients (59%) who were assigned to undergo CABG alone and in 289 patients (58%) who were assigned to undergo CABG with surgical ventricular reconstruction. The authors concluded that although adding surgical ventricular reconstruction to CABG reduced the left ventricular volume, as compared with CABG alone, this anatomical change was not associated with a greater improvement in symptoms or exercise tolerance or with a reduction in the rate of death or hospitalization for cardiac causes.

The ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult state that although a variant of the aneurysmectomy procedure is now being developed for the management of patients with ischemic cardiomyopathy, its role in the management of HF remains to be defined. None of the current surgical reconstruction techniques offer “rescue therapy” to patients with critical hemodynamic compromise.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: 33548 (E/I) Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, DOR procedure)

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HCPCS: No specific code(s)

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ICD9: Investigational for all diagnoses

ICD10: Investigational for all diagnoses

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* key article

KEY WORDS:

DOR procedure, Surgical anterior endocardial restoration (SAVER), Surgical ventricular restoration (SVR), Ventricular remodeling.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, surgical ventricular restoration (Dor procedure) is not specifically addressed in National or Regional Medicare coverage determinations or policies.