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Surgical Ventricular Restoration

Policy # 00184
Original Effective Date: 01/26/2006
Current Effective Date: 03/19/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data the Company considers surgical ventricular restoration for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm to be **investigational**.*

Background/Overview

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 may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER), left ventricular reconstructive surgery, left ventricular aneurysmectomy reconstruction, endoventricular circular plasty, or the Dor procedure after Vincent Dor, MD. Dr. Dor pioneered the expansion of techniques for ventricular reconstruction and is credited with treating heart failure patients with SVR in conjunction with coronary artery bypass grafting (CABG).

The SVR procedure is usually performed after 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 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The CorRestore™‡ Patch System is a device approved by the U.S. 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.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination.

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Rationale/Source

The most recent literature search was performed for the period of June 2012 through June 2013. Following is a summary of the key literature to date with a focus on controlled trials:

At the time this policy was created, a review of the peer-reviewed literature on MEDLINE revealed many publications on a variety of approaches to SVR. These publications primarily consisted of case series reports and retrospective reviews from single centers, with the exception of publications from the multicenter Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the Left Ventricle (RESTORE) Group. The RESTORE Group is an international group of cardiologists and surgeons from 13 centers that had investigated SVR for the past 20 years in more than 1,000 patients with ischemic cardiomyopathy following anterior infarction. While the SVR procedure had been performed for many years, the available data were inadequate to permit conclusions regarding health benefits associated with SVR. Specifically, the lack of any randomized controlled trials (RCTs) comparing SVR to other surgical or medical therapies did not permit scientific assessment of the efficacy of SVR. In addition, patient selection criteria and optimal surgical techniques were still undetermined.

In 2002, a randomized, multicenter international clinical trial on the Surgical Treatment of Ischemic Heart Failure (STICH) was initiated to compare medical therapy with CABG and/or SVR for patients with heart failure and coronary heart disease (ClinicalTrials.gov Identifier: NCT00023595). The STICH trial was sponsored by the National Heart, Lung, and Blood Institute and was expected to recruit 2,800 patients with heart failure, left ventricular ejection fraction <0.35, and coronary artery disease amenable to CABG at 50 clinical sites. Patients with extensive anterior ischemia assigned to the surgical arm of the study were to be further randomized to CABG surgery alone versus bypass surgery plus SVR. The 2009 results of this trial, as well as a representative sample of some of the earlier case series on SVR, are discussed below.

Controlled Trials

In 2006, Ribeiro and colleagues from Brazil reported on 137 patients with anterior myocardial infarction (MI) and ejection fraction less than 50%. Those patients who had viable anterior myocardium were randomized to SVR or SVR plus revascularization, and those patients with nonviable anterior myocardium received SVR. Ejection fraction improved in all groups, but the most improvement was in the SVR plus revascularization group.

Results of the National Heart, Lung, and Blood Institute-sponsored STICH trial were published in 2009. This study was a multicenter, unblinded RCT performed at 127 clinical sites from 26 countries. A total of 1,000 patients with coronary artery disease and ejection fraction of 35% or less were randomized to CABG alone (n=499) or CABG plus SVR (n=501). The primary outcome was a composite of death from any cause and hospitalization for cardiac reasons. While SVR reduced the end-systolic volume index by 19% compared to 6% with CABG alone, there was no difference between groups in the primary outcome, which occurred in 292/499 (59%) of the CABG alone group compared to 289/501 (58%) of the CABG + SVR group (hazard ratio [HR]: 0.99, 95% confidence interval [CI]: 0.84-1.17, p=0.90). Death from any cause occurred in 141/499 (28%) in the CABG alone group compared to 138/501 (28%) in the CABG + SVR group (HR: 1.00, 95% CI: 0.79-1.26, p=0.98). Cardiac symptoms and exercise tolerance also improved to similar degrees between groups. Other secondary outcomes, such as stroke, MI, and subsequent procedures, also did not

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differ between groups. Subgroup analysis did not reveal any patient groups that benefited from SVR significantly more than the entire group.

STICH investigators have subsequently conducted additional analyses in attempts to identify patient groups that might have improved outcomes with CABG and SVR over CABG alone. Subgroup analyses reported a trend suggesting patients with better preoperative left ventricular function, using measures such as left-ventricular ejection fraction (LVEF), end-systolic volume index and/or end-diastolic volume index might benefit from SVR, but subgroup differences did not reach statistical significance. For example, in the subgroup of patients with an LVEF of 33% or higher, the hazard ratio for the primary outcome was 0.77 (95% CI: 0.55-1.08), while in patients with an LVEF of 25% or less, the hazard ratio was 1.42 (95% CI: 1.02-1.98). Since these subgroup analyses were performed post-hoc and no statistically significant differences were reported, the results are inconclusive.

A separate publication from the STICH trial reported on quality-of-life (QOL) outcomes. The main QOL outcome measure used was the Kansas City Cardiomyopathy Questionnaire (KCCQ), which is a 23-item scale meant to measure the effect of heart failure symptoms on QOL. Secondary QOL measures included the Seattle Angina Questionnaire, the short form (SF)-12, the CES-D depression measure, the Cardiac Self-Efficacy Questionnaire, and the EuroQoL 5-D. The questionnaires were administered at baseline and 4, 12, 24, and 36 months post-randomization. Available numbers of patients at each time point were 991, 897, 828, 751, and 669, respectively. Scores on the KCCQ QOL measures improved for both groups to a similar degree; there was no incremental benefit for the SVR group compared to the CABG alone group. Similarly, there were no group differences noted on any of the secondary QOL measures.

A second RCT was published in 2011 by Marchenko et al. This was a study performed in Russia of 236 patients with ischemic heart failure who were randomized to CABG alone or CABG + SVR. The mean follow-up was 31$\pm$13 months. Outcome measures reported were perioperative mortality and survival at 1-, 2-, and 3-year follow-up. Perioperative mortality was 5.8% in the CABG alone group compared with 3.5% in the CABG + SVR group (p=NS, statistical tests not reported). Survival at 1 and 3 years was 95% and 78%, respectively, in the CABG + SVR group, compared with 83% and 78%, respectively, in the CABG alone group (statistical tests not reported). There were reductions in New York Heart Association (NYHA) functional class and angina class for both groups after surgery, but between-group statistical testing was not reported. For example, the NYHA functional class decreased in the CABG + SVR from 3.1$\pm$0.4 at baseline to 2.2$\pm$0.6 at 3 years, compared with a decrease in the CABG alone group from 2.9$\pm$0.5 to 2.4$\pm$0.9.

Uncontrolled Studies

Athanasuleas and colleagues from the RESTORE Group, reported on early and 3-year outcomes in 662 patients who underwent SVR following anterior MI during the period of January 1998 to July 2000. In addition to SVR, patients also concomitantly underwent CABG (92%), mitral repair (22%), and mitral replacement (3%). The authors reported overall mortality during hospitalization was 7.7%; postoperative ejection fractions increased from 29.7% $\pm$ 11.3% to 40.0% $\pm$ 12.3% (p<0.05). The survival rate and freedom from hospitalization for heart failure at 3 years was 89.4% $\pm$ 1.3% and 88.7%, respectively. In a separate publication on 439 patients from the RESTORE Group, Athanasuleas and coworkers reported outcomes

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improved in patients with lower patient age, higher ejection fractions, and lack of need for mitral valve replacement.

Mickleborough and colleagues reported on 285 patients who underwent SVR by a single surgeon for class III or IV heart failure, angina, or ventricular tachyarrhythmia during the period of 1983 to 2002. In addition to SVR, patients also concomitantly underwent CABG (93%), patch septoplasty (22%), arrhythmia ablation (41%), mitral repair (3%), and mitral replacement (3%). SVR was performed on the beating heart in 7% of patients. The authors reported hospital mortality of 2.8%; postoperative ejection fractions increased 10% $\pm$ 9% from 24% $\pm$ 11% ($p<0.000$), and symptom class in 140 patients improved 1.3 $\pm$ 1.1 functional class per patient. Patients were followed for up to 19 years (mean, 63 $\pm$ 48 months), and overall actuarial survival was reported as 92%, 82%, and 62% at 1, 5, and 10 years, respectively. The authors suggested wall-thinning should be used as a criterion for patient selection.

Bolooki and colleagues reported on 157 patients who underwent SVR by a single surgeon for class III or IV heart failure, angina, ventricular tachyarrhythmia, or MI using 3 operative methods during the period of 1979 to 2000. SVR procedures consisted of radical aneurysm resection and linear closure (n=65), septal dyskinesis reinforced with patch septoplasty (n=70), or ventriculotomy closure with an intracavitary oval patch (n=22). The authors reported hospital mortality of 16%. The mean preoperative ejection fraction was 28% $\pm$ 0.9%. Patients were followed up for up to 22 years, and overall actuarial survival was reported as 53%, 30%, and 18% at 5, 10, and 15 years, respectively. The authors found factors improving long-term survival included SVR with intraventricular patch repair and ejection fraction of 26% or greater preoperatively.

Sartipy and colleagues reported on 101 patients who underwent SVR using the Dor procedure at a single center for class III or IV heart failure, angina, and ventricular tachyarrhythmia during the period of 1994 to 2004. In addition to SVR, patients also concomitantly underwent CABG (98%), arrhythmia ablation (52%), and mitral valve procedure (29%). The authors reported early mortality (within 30 days of operation) was 7.9%; left ventricular ejection fraction increased from 27% $\pm$ 9.9% to 33% $\pm$ 9.3% postoperatively. Patients were followed up 4.4 $\pm$ 2.8 years, and overall actuarial survival was reported as 88%, 79%, and 65% at 1, 3, and 5 years, respectively.

In 2006, Hernandez et al. reported on the contemporary performance of SVR based on data from the Society of Thoracic Surgeons' (STS) database. From January 2002 to June 2004, 731 patients underwent procedures at 141 hospitals. The operative mortality was 9.3%; combined death or major complications occurred in 33.5%. The authors commented that further studies of SVR are needed to improve patient selection and procedural performance. Tulner et al. reported on 6-month follow-up on 21 patients with ischemic dilated cardiomyopathy who underwent SVR and bypass grafting; some also had valve annuloplasty. Improvement in a number of clinical variables was noted, including decreased left-ventricular dyssynchrony, reduced tricuspid regurgitation, and improved ejection fraction (27–36%).

Searches of the MEDLINE database have found that the published studies continue to primarily report on case series. In many, SVR was performed in conjunction with additional cardiac procedures. For example, Tulner et al. reported on 6-month outcomes on 33 patients with class III/IV heart failure who underwent SVR

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and/or restrictive mitral annuloplasty. Operative mortality was 3%, and additional in-hospital mortality was 9%. Quality-of-life scores improved, as did 6-minute walking distance (248 to 422 meters). Williams et al. reported on a retrospective review of outcomes following SVR in a series of 34 patients with New York Heart Association (NYHA) class IV heart failure and 44 patients with class II/III who had surgery between January 2002 and December 2005. There were 3 operative deaths in each group. While there was symptomatic improvement in both groups, there was a trend toward reduced survival at 32 months in those with class IV versus class II/III disease (68% vs. 88%, respectively). A non-randomized comparative study from Europe involving patients with coronary artery disease who underwent CABG or CABG plus SVR and had an ejection fraction of 30% to 40% was published in 2009. In this non-randomized study, the authors concluded that patients in whom SVR was possible experienced more perioperative complications but had improved early and midterm outcomes. While these and similar studies show that some clinical improvement occurs following this surgery, the non-randomized nature of these studies limits the ability to draw conclusions. Controlled trials are needed to compare the outcomes of SVR to other alternatives.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov in July 2013 found one active Phase III trial on surgical ventricular restoration. The STICH study is a randomized, multicenter, international, clinical trial to compare medical therapy with CABG and/or SVR for patients with heart failure and coronary heart disease (NCT00023595). Although this trial is listed as ongoing, it is no longer recruiting patients and the main results of the CABG alone versus CABG plus surgical ventricular restoration have already been published and are reviewed in this reference policy.

Summary

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. 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 these data, the impact of SVR on net health outcome remains uncertain. Therefore, SVR is considered investigational.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33548
HCPCS	No codes
ICD-9 Diagnosis	All relative diagnosis
ICD-9 Procedure	37.35

Policy History

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01/04/2006	Medical Director review
01/17/2006	Medical Policy Committee review
01/26/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. No change to coverage.
01/07/2010	Medical Policy Committee approval
01/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2011	Medical Policy Committee review
01/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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