BlueCross BlueShield of Alabama

Name of Policy:
Surgical Ventricular Restoration

Policy #: 257
Category: Surgery

Latest Review Date: August 2014
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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 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 surgical ventricular restoration 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 >3cm), 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 (i.e., the Batista procedure), 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), left ventricular reconstructive surgery, left ventricular aneurysmectomy reconstruction, endoventricular circular plasty, or the Dor procedure after Vincent Dor, M.D. Dr. Dor pioneered expansion of techniques for ventricular reconstruction and is credited with treating congestive heart failure patients with SVR in conjunction with CABG.

Policy:

Surgical ventricular restoration does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** for the treatment of ischemic dilated cardiomyopathy or post infarction left ventricular aneurysm.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was originally created in 2005 and has been regularly updated with searches of the MEDLINE database. The most recent literature search was performed for the period of June 2013 through July 20, 2014. 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 surgical ventricular restoration (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 1000 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 January 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 congestive heart failure and coronary heart disease. The STICH trial is sponsored by the National Heart, Lung, and Blood Institute and will recruit 2,800 patients with heart failure, left ventricular ejection fraction < .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 will 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.

Uncontrolled Studies

Athanasuleas et al from the RESTORE Group, reported on early and three-year outcomes in 662 patients who underwent SVR following anterior myocardial infarction 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% ± 11.3% to 40.0% ± 12.3% ($P < .05$). The survival rate and freedom from hospitalization for heart failure at three years was 89.4% ± 1.3% and 88.7% respectively. In a separate publication on 439 patients from the RESTORE Group, Athanasuleas et al reported outcomes improved in patients with lower patient age, higher ejection fractions and lack of need for mitral valve replacement.

Mickleborough et al reported on 285 patients who underwent SVR by a single surgeon for Class III or IV congestive 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% ± 9% from 24% ± 11% ($p<.000$) and symptoms class in 140 patients improved 1.3 ± 1.1 functional class per patient. Patients were followed up for up to 19 years (mean, 63 ± 48 months) and overall actuarial survival was reported as 92%, 82%, and 62% at one, five and ten years respectively. The authors suggested wall-thinning should be used as a criterion for patient selection.

Bolooki et al reported on 157 patients that underwent SVR by a single surgeon for Class III or IV congestive heart failure, angina, ventricular tachyarrhythmia or myocardial infarction using three operative methods during the period of 1979 to 2000. SVR procedures consisted of radical aneurysm resection closure with an intracavitary oval patch (n = 22). The authors reported hospital mortality of 16%. The mean preoperative ejection fraction was 28% ± 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 et al reported on 101 patients who underwent SVR using the Dor procedure at a single center for class III or IV congestive 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% ± 9.9% to 33% ± 9.3% postoperatively. Patients were followed up 4.4 ± 2.8 years and overall actuarial survival was reported as 88%, 79%, and 65% at one, three and five years respectively.

While the SVR procedure has been performed for many years, the available data are 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.

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 six-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 continued to primarily report on case series. In many, SVR was performed in conjunction with additional cardiac procedures. For example, Tulner et al reported on six-month outcomes on 33 patients with class III/IV heart failure who underwent SVR and/or restrictive mitral annuloplasty. Operative mortality was 3%, and additional in-hospital mortality was 9%. Quality-of-life scores improved as did six-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 three 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 nonrandomized 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 nonrandomized 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 this treatment to other alternatives.

Controlled Trials

In 2006, Ribeiro et al from Brazil reported on 137 patients with anterior 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 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 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+13 months. Outcome measures reported were perioperative mortality and survival at one, two, and three years' 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 one and three 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 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+0.4 at baseline to 2.2+0.6 at 3 years, compared with a decrease in the CABG alone group from 2.9+0.5 to 2.4+0.9.

Summary

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 postinfarction 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 randomized controlled trial, the Surgical Treatment of Ischemic Heart Failure (STICH) trial, did not report any improvements in clinical outcomes or quality-of-life measures for patients undergoing SVR in addition to standard coronary artery bypass grafting (CABG) surgery. As a result of these data, the impact of SVR on net health outcome remains uncertain. Therefore, SVR is considered investigational.

Practice Guidelines and Position Statements

In 2010, a Task Force of the European Society of Cardiology and the European Association for Cardio- Thoracic Surgery developed guidelines on myocardial revascularization. These guidelines consider SVR combined with CABG to be a surgical option for patients with ischemic heart failure and left ventricular ejection fraction of 35% or less (based on opinion and evidence that is not well-established). The guidelines also recommend SVR with CABG only be performed in centers with a high level of surgical expertise.

U.S. Preventive Services Task Force Recommendations

Surgical ventricular restoration is not a preventive service.

Key Words:
DOR procedure, surgical anterior endocardial restoration (SAVER), surgical ventricular restoration (SVR), ventricular restoration or remodeling

Approved by Governing Bodies:
The CorRestore™ Patch System is a device cleared by the U.S. Food and Drug Administration 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. Product code: DXZ.

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:
CPT Codes:	**33548**	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, DOR procedure)

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Policy History:

Medical Policy Group, October 2005 **(3)**
Medical Policy Administration Committee, October 2005
Medical Policy Group, October 2007 **(1)**
Medical Policy Group, October 2009 **(1)**
Medical Policy Group, August 2011 **(1):** Update to Description, Key Points and References, no change in policy statement
Medical Policy Group, August 2012 **(4):** Updated Key Points and References. No change in policy statement.
Medical Policy Group August 2013 **(4):** Updated Key Points and Reference. No changes to the policy statement.
Medical Policy Panel, August 2014
Medical Policy Panel, August 2014 **(3)**: 2014 Updates – no additional information/literature available for review; no changes to policy statement