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.

**Related Policies**

- N/A

**Policy**

Surgical ventricular restoration is considered investigational for the treatment of ischemic dilated cardiomyopathy or postinfarction left ventricular aneurysm.

**Policy Guidelines**

The following CPT code is available for reporting this procedure:

- 33548: Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER [surgical anterior ventricular endocardial restoration], DOR procedures)

Surgical ventricular restoration involves increased physician work compared with standard ventriculectomy. For example, the procedure includes evaluation of the ventricular septum and reshaping of the geometry of the heart. Surgical ventricular restoration is described as a global treatment of left ventricular failure, while conventional left ventricular aneurysmectomy represents a local treatment of a transmural infarct.

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as
investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Rationale

#### Background

The SVR procedure may also be referred to as ventricular remodeling, SAVER, left ventricular reconstructive surgery, left ventricular aneurysmectomy reconstruction, endoventricular circular plasty, or the Dor procedure named 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 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 (i.e., the Batista procedure, see Policy No. 7.01.66), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

#### Regulatory Status

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.

#### Rationale

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 2002, a randomized, multicenter international clinical trial on the Surgical Treatment of Ischemic Heart Failure (STICH) was initiated to compare medical therapy with coronary artery bypass grafting (CABG) and/or SVR for patients with heart failure and coronary heart disease (NCT00023595). The STICH trial was sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and was expected to recruit 2800 patients with heart failure, left ventricular ejection fraction less than 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 et al 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 NHLBI-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 1000 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 with 6% with CABG alone, there was no difference between groups in the primary outcome, which occurred in 292 of 499 (59%) of the CABG alone group compared with 289 of 501 (58%) of the CABG + SVR group (hazard ratio [HR], 0.99; 95% confidence interval [CI], 0.84 to 1.17; p = 0.90). Death from any cause occurred in 141 of 499 (28%) in the CABG alone group compared with 138 of 501 (28%) in the CABG + SVR group (HR = 1.00; 95% CI: 0.79 to 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, 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 were not statistically significant. For example, in the subgroup of patients with an LVEF of 33% or higher, the HR for the primary outcome was 0.77 (95% CI, 0.55 to 1.08), while in patients with an LVEF of 25% or less, the HR was 1.42 (95% CI, 1.02 to 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 12-Item Short-Form Health Survey, the Center for Epidemiologic Studies Depression Scale, the Cardiac Self-Efficacy Questionnaire, and the EuroQoL 5-D. The questionnaires were administered at baseline and 4, 12, 24, and 36 months postrandomization. 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 with 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±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 test 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, NYHA functional class decreased in the CABG + SVR group 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.

Uncontrolled Studies

Athanasuleas et al 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 that overall mortality during hospitalization was 7.7%; postoperative ejection fractions increased from 29.7%±11.3% to 40.0%±12.3% (p<0.05). The survival rate and freedom from hospitalization for heart failure at 3 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 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<0.000), and symptom class in 140 patients improved 1.3±1.1 functional classes per patient. Patients were followed for up to 19 years (mean, 63±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 et al 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 28%±9.9%. 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 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%; LVEF 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 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 and/or restrictive mitral annuloplasty. Operative mortality was 3%, and additional in-hospital mortality was 9%. QOL scores improved, as did 6-minute walking distance (248-422 meters). Williams et al reported on a retrospective review of outcomes following SVR in a series of 34 patients with 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 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 nonrandomized nature of these studies limits the ability to draw conclusions. Controlled trials are needed to compare the outcomes of SVR to other alternatives.

Ongoing and Unpublished Clinical Trials

An online search of ClinicalTrials.gov on July 20, 2014, found 1 active phase 3 trial on surgical ventricular restoration. The Surgical Treatment of Ischemic Heart Failure (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

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.

Supplemental Information

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.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


Documentation Required for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, Dor procedures)</td>
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<td>Excision right ventricle open</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<td>11/26/2014</td>
<td>BCBSA Medical Policy adoption</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.