



Louisiana

Surgical Ventricular Restoration

Policy # 00184

Original Effective Date: 01/26/2006

Current Effective Date: 05/16/2018

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 (SVR) for the treatment of ischemic dilated cardiomyopathy to be **investigational**.*

Background/Overview

Surgical ventricular restoration is also known as surgical anterior ventricular endocardial restoration (SAVER), left ventricular reconstructive surgery, 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 and coronary artery bypass grafting (CABG).

SVR is usually performed after 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 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2004, the CorRestore™ Patch System (Somanetics Corp.) was cleared for marketing by the U.S. FDA through the 510(k) process 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.

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Centers for Medicare and Medicaid Services (CMS)

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

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

SURGICAL VENTRICULAR RESTORATION

Randomized Controlled Trials

In 2002, the international Surgical Treatment of Ischemic Heart Failure (STICH) trial was initiated to compare medical therapy with CABG and/or SVR for patients with heart failure and coronary heart disease (NCT00023595). This trial was sponsored by the National Heart, Lung, and Blood Institute. Results of the STICH trial were published in 2009 (see Tables 1 and 2). This unblinded trial was performed at 127 clinical sites in 26 countries. The STICH trial tested two hypotheses, examining the effect of (1) medical therapy vs medical therapy plus CABG and (2) medical therapy plus CABG vs medical therapy plus CABG and SVR. Focusing on testing of the second hypothesis, a total of 1000 patients with coronary artery disease and an ejection fraction of 35% or less were randomized to CABG alone (n=499) or CABG plus SVR (n=501) (see Table 2). The primary outcome was a composite of death from any cause and hospitalization for cardiac reasons.

Table 1. Summary of Key RCT Characteristics

Author; Study	Countries	Sites	Dates	Participants ^a	Interventions	
					Active	Comparator
Jones et al	U.S., Canada,	127	2002-2007	• Patients with CAD treatable with	Medical	Medical therapy

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(2009) ¹ ; STICH	South America, Europe, Asia	CABG, and LVEF \leq 35% • Exclusion for recent MI, need for AV replacement, planned PCI, or life expectancy <3 y	therapy + CABG + SVR	+ CABG
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AV: aortic valve; CAD: coronary artery disease; CABG: coronary artery bypass grafting; LVEF: left ventricular ejection fraction; MI: myocardial infarction; PCI: percutaneous coronary intervention; RCT: randomized controlled trial; SVR: surgical ventricular restoration.

^a Key eligibility criteria.

Table 2. Summary of Key RCT Results

Study	Primary Outcomes			Secondary Outcomes		
	Death From Any Cause	Hospitalization for Cardiac Causes	Hospitalization for Any Cause	Death From Any Cause at 30 days (ITT)	Acute MI	Stroke
Jones et al (2009) ¹						
CABG (n=499)	141 (28)	211 (42)	272 (55)	25 (5)	22 (4)	31 (6)
CABG + SVR (n=501)	138 (28)	204 (41)	268 (53)	26 (5)	20 (4)	23 (5)
HR (95% CI)	1.00 (0.79 to 1.26)	0.97 (0.83 to 1.18)	0.98 (0.83 to 1.16)		1.01 (0.54 to 1.87)	0.77 (0.45 to 1.32)
p	0.98	0.73	0.82	0.88	0.96	0.35

Values are n (%), unless otherwise indicated. CABG: coronary artery bypass grafting; CI: confidence interval; HR: hazard ratio; MI: myocardial infarction; RCT: randomized controlled trial; SVR: surgical ventricular restoration.

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. Cardiac symptoms and exercise tolerance also improved to similar degrees between groups. Other secondary outcomes, such as stroke, myocardial infarction, and subsequent procedures, did not differ between groups. Subgroup analyses did not reveal any patient groups that benefited from SVR significantly more than the entire group.

STICH investigators subsequently conducted additional analyses to identify patient groups that might have improved outcomes with CABG plus SVR over CABG alone. A 2014 analysis evaluated whether, in the STICH trial, myocardial viability was associated with patient outcomes. A total of 267 patients underwent single-photon emission computed tomography viability studies, and 191 were found to have myocardial viability. The investigators found no significant interaction between myocardial viability status and treatment group for the outcomes mortality (p=0.36) or mortality plus cardiac hospitalization (p=0.55).

Subgroup analyses published in 2013 did not find significantly improved outcomes in patients with better preoperative left ventricular function, using measures such as left ventricular ejection fraction, end-systolic volume index, and/or end-diastolic volume index. A 2015 subgroup analysis found that patients with moderate-to-severe preoperative right ventricular dysfunction had worse outcomes when they underwent SVR plus CABG than CABG alone. In an analysis adjusting for other prognostic factors, the interaction between right ventricular function and treatment group was statistically significant for all-cause mortality (p=0.022). A 2017 subgroup analysis found that left ventricular end-systemic volume index was the most important predictor of mortality following CABG or CABG plus SVR; the study also established that mortality

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following SVR was not predicted by left ventricular regional dysfunction. Because subgroup analyses were performed post hoc, they are considered hypothesis generating, and findings would need to be confirmed in prospective trials.

A separate 2009 publication from the STICH trial reported on quality of life (QOL) outcomes. The main QOL outcome measurement tool used was the Kansas City Cardiomyopathy Questionnaire, which is a 23-item scale that assesses 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 Kansas City Cardiomyopathy Questionnaire 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 randomized controlled trial was published by Marchenko et al (2011). Performed in Russia, this study randomized 236 patients with ischemic heart failure to CABG alone or CABG plus SVR. The authors noted that “most” of the patients in the trial were also included in the STICH trial. Mean follow-up was 31 months. Outcome measures reported were perioperative mortality and survival at 1-, 2-, and 3-year follow-ups. Perioperative mortality was 5.8% in the CABG alone group compared with 3.5% in the CABG plus SVR group ($p=NS$). Survival at 1 and 3 years was 95% and 78%, respectively, in the CABG plus SVR group, compared with 83% and 78%, respectively, in the CABG alone group (statistical comparisons not reported). There were reductions in New York Heart Association functional and angina classes for both groups after surgery, but between-group statistical testing was not reported. For example, mean New York Heart Association functional class decreased in the CABG plus SVR group from 3.1 at baseline to 2.2 at 3 years, compared with a decrease in the CABG alone group from 2.9 to 2.4.

Section Summary: Randomized Controlled Trials

Two randomized controlled trials have examined SVR for the treatment of ischemic dilated cardiomyopathy—the large multicenter National Heart, Lung, and Blood Institute–sponsored STICH trial and a smaller single center Russian study that included patients enrolled in STICH. The STICH trial failed to demonstrate benefit from SVR. Overlap in the patients reported in the second trial limits any implications of its results.

Uncontrolled Studies

The Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the LV (RESTORE) Group is an international group of cardiologists and surgeons from 13 centers that investigated SVR in more than 1000 patients with ischemic cardiomyopathy following anterior infarction. Athanasuleas et al (2001), from the RESTORE Group, reported on early and 3-year outcomes in 662 patients who underwent SVR following anterior myocardial infarction between 1998 and 2000. In addition to SVR, patients concomitantly underwent CABG (92%), mitral repair (22%), and mitral replacement (3%). The

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authors reported that overall mortality during hospitalization was 7.7%; postoperative ejection fractions increased from 29.7% to 40.0% ($p < 0.05$). The survival rate and freedom from hospitalization for heart failure at 3 years was 89.4% and 88.7%, respectively. In a separate 2001 publication on 439 patients from the RESTORE Group, Athanasuleas et al reported that outcomes improved in younger patients, those with higher ejection fractions, and those not needing mitral valve replacement.

Mickleborough et al (2004) 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 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% from 24% ($p < 0.000$), and symptom class in 140 patients improved 1.3 functional classes per patient. Patients were followed for up to 19 years (mean, 63 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 (2003) reported on 157 patients who underwent SVR by a single surgeon for class III or IV heart failure, angina, ventricular tachyarrhythmia, or myocardial infarction using 3 surgical methods from 1979 to 2000. SVR procedures consisted of radical aneurysm resection and linear closure ($n=65$), septal dyskinesia reinforced with patch septoplasty ($n=70$), or ventriculotomy closure with an intracavitary oval patch ($n=22$). The authors reported hospital mortality of 16%. Mean preoperative ejection fraction was 28%. Patients were followed 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 (2005) 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 from 1994 to 2004. In addition to SVR, patients concomitantly underwent CABG (98%), arrhythmia ablation (52%), and mitral valve procedure (29%). The authors reported early mortality (within 30 days of surgery) was 7.9%; left ventricular ejection fraction increased from 27% to 33% postoperatively. Patients were followed for 4.4 years, and overall actuarial survival was reported as 88%, 79%, and 65% at 1, 3, and 5 years, respectively.

Hernandez et al (2006) reported on the contemporary performance of SVR based on data from the Society of Thoracic Surgeons' database. From 2002 to 2004, 731 patients underwent procedures at 141 hospitals. The operative mortality was 9.3%; combined death or major complications occurred in 33.5%. Tulner et al (2006) reported on 6-month follow-up for 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%).

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In a number of reports, SVR has been performed in conjunction with additional cardiac procedures. For example, Tulner et al (2007) reported on 6-month outcomes for 33 patients with class III or 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 (2007) retrospectively reviewed outcomes following SVR in a series of 34 patients with New York Heart Association class IV heart failure and 44 patients with class II or III heart failure who had surgery between 2002 and 2005. There were 3 operative deaths in each group. While symptoms improved in both groups, there was a trend toward reduced survival at 32 months in those with class IV (68%) vs class II or III disease (88%). A 2009 nonrandomized comparative study from Europe involving patients with coronary artery disease who underwent CABG or CABG plus SVR reported an ejection fraction of 30% to 40%. 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. Ohira et al (2017) reported on 44 consecutive patients who underwent a modified SVR procedure, many done in conjunction with CABG (93%) or mitral valve repair or replacement (58%). Operative mortality was 11%. Patients demonstrated improvements in ejection fraction as well as end-systolic LV volume index after the procedure.

Section Summary: Uncontrolled Studies

While these and similar uncontrolled studies have shown some clinical improvements following surgery plus SVR, the nonrandomized nature of these studies limits the ability to draw conclusions. Controlled trials are needed to compare SVR outcomes with other alternatives.

SUMMARY OF EVIDENCE

For individuals who have ischemic dilated cardiomyopathy who receive SVR as an adjunct to CABG, 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. 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 CABG 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.

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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

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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.
03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval.. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/03/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval.. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. Deleted "or postinfarction left ventricular aneurysm" from the policy statement.
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date:	05/2019

Coding

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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-10 Diagnosis	All related diagnoses

*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);
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