Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Surgical Ventricular Restoration (SVR)

Description/Background

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.

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), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

Regulatory Status

In 2004, the CorRestore™ Patch System (Somanetics Corp.) was cleared for marketing by the U.S. Food and Drug Administration 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.

In 2020, Ancora Heart announced that it received an FDA investigational device exemption for its AccuCinch® ventricular restoration system. This exemption allows Ancora Heart to proceed with an initial efficacy and safety study in patients with heart failure and reduced ejection fraction.

Medical Policy Statement

Surgical ventricular reconstruction is experimental/investigational. SVR has not been scientifically demonstrated to improve clinical outcomes in patients with heart failure.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

33548

Rationale

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

Clinical Context and Therapy Purpose
The purpose of SVR as an adjunct to standard coronary artery bypass grafting (CABG alone) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as coronary artery bypass grafting, in patients with ischemic dilated cardiomyopathy.

The following **PICOs** were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with ischemic dilated cardiomyopathy.

Interventions
The therapy being considered is SVR as an adjunct to standard CABG.

Comparators
The main comparator of interest is CABG alone.

Outcomes
The general outcomes of interest are overall survival, symptoms, QOL, hospitalizations, resource utilization, and treatment-related morbidity. Symptoms of ischemic dilated cardiomyopathy may include heart palpitations, angina, edema, shortness of breath, dizziness or syncope, and fatigue.

The existing literature, particularly the Surgical Treatment of Ischemic Heart Failure (STICH) trial and its subsequent subgroup analyses, that evaluate SVR as an adjunct to standard CABG as a treatment for ischemic dilated cardiomyopathy has varying lengths of follow-up, 4 months to 19 years. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, long-term follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

In 2002, the 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 surgical ventricular restoration (SVR) for patients with heart failure and coronary heart disease (NCT00023595). This trial was sponsored by the National Heart, Lung, and Blood Institute (NHLBI). Results of the STICH trial were published in 2009 (Tables 1 and 2).[1] This unblinded study was performed at 127 clinical sites in 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) (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

					Interventions	
Author; Study	**Countries**	**Sites**	**Dates**	**Participants[a]**	**Active**	**Comparator**
Jones et al (2009)[1]; STICH	U.S., Canada, South America, Europe, Asia	127	2002-2007	• Patients with CAD treatable with CABG, and LVEF ≤35% • Exclusion for recent MI, need for AV replacement, planned PCI, or life expectancy <3 y	Medical therapy + CABG + SVR	Medical therapy + CABG

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

	Primary Outcomes			Secondary Outcomes		
Study	**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; ITT: intention to treat.

Table 3. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Jones et al (2009)[1] STICH			2.Volume studies were not conducted for 66% of trial participants	6.The STICH trial's 300 surgically treated patients in 12 centers had 6% mortality (range 3%-12%); much higher than the 1% mortality reported in 1978 of 1000 patients from the Cleveland Clinic	

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Jones et al (2009)[1] STICH		1,3.physicians and surgeons caring for patients were aware of the treatment received.	2.The STICH trial reports the intervention successful despite the higher mortality rate than other non-participating centers			

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

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 have improved outcomes with CABG and SVR over CABG alone. A 2014 analysis evaluated whether, in the STICH study, myocardial viability was associated with patient outcomes.[2] A total of 267 patients in the study 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 better outcomes in 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.[3,4] A 2015 sub-analysis found that patients with moderate-to-severe preoperative right ventricular dysfunction had worse outcomes when they underwent SVR plus CABG compared with CABG alone.[5] 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 following SVR was not predicted by left ventricular regional dysfunction.[6] 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.[7] 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 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 (2011).[8] 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 31months. Outcome measures reported were perioperative mortality and survival at 1, 2, and 3 years 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 (NYHA) functional class and angina classes for both groups after surgery, but between-group statistical testing was not reported. For example, the NYHA functional class decreased in the CABG plus SVR 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.

Nonrandomized Trials

Tables 5 and 6, below, summarize the characteristics and results of key nonrandomized trials and observational studies (n=6), including five cohort studies and one comparative review comparing SVR to other surgical interventions in multiple populations. The studies range in size (range n 101-731) and duration of follow-up (up to 22 years). The studies, as a whole, show some clinical improvements when SVR is utilized in the target patient population as a surgical intervention.

Table 5. Summary of Key Nonrandomized Trial Characteristics

Study	Study Type	Country	Dates	Participants	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Follow-Up
Athanasuleas (2001)[9]	Cohort	US, Monaco, Italy	1998-2000	Who underwent SVR after anterior myocardial infarction with or without concomitant procedures (n=662)	SVR+ CABG (n=609)	SVR= Mitral repair (n=146)	SVR+ mitral replacement (n=20)		3 y
Athanasuleas (2001)[10]	Cohort	US, Monaco, Italy	1998-1999	who underwent SVR after anterior myocardial infarction with or without concomitant procedures (n=439)	SVR+CABG (n=391)	SVR= Mitral repair (n=97)	SVR+ mitral replacement (n=18)		18 m
Mickleborough (2004)[11]	Cohort	CA	1983-2002	who underwent SVR for Class III or IV heart failure, angina, or ventricular tachyarrhythmia with or without concomitant procedures (n=285)	SVR+CABG (n=63)	SVR+ arrythmia ablation (n=117)	SVR+mitral repair (n=9)	SVR+mitral replacement (n=9)	≤19 y; mean 63-m
Bolooki (2003)[12]	Cohort	US	1997-2000	who underwent SVR for Class III or IV heart failure, angina, ventricular tachyarrhythmia or myocardial infarction (n=157)	Radical aneurysm resection+ linear closure (n=65)	Septal dyskinesia reinforced with patch septoplasty (n=70)	Ventriculotomny closure+ intracavitary oval patch (n=22)		≤22 y
Sartipy (2005)[13]	Cohort	Sweden	1994-2004	who underwent SVR using Dor procedure for Class III or IV heart failure, angina, or ventricular tachyarrhythmia with or without concomitant procedures (n=101)	SVR+CABG (n=99)	SVR+ arrythmia ablation (n=53)	SVR+ mitral valve procedure (n=29)		5 y
Hernandez (2006)[14]	CS	US	2002-2004	Patient data from the Society of Thoracic	SVR procedure (n=731)				

				Surgeons' database					

CS: comparative study; y:year; m: month(s); CABG: coronary artery bypass grafting; SVR: surgical ventricular restoration.

Table 6. Summary of Key Nonrandomized Trials Study Results

Study	In-Hospital Mortality	↑ in Post-operative ejection Fraction	↓ in Left Ventricular End Systolic Volume Index	Survival Rate (Post-op year)	Freedom From Hospitalization
Athanasuleas (2001)[9] (n=662)	7.7%	10.3% (p<0.05)		89.4% (3)	88.7% (3)
Athanasuleas (2001)[10] (n=439)	6.6%	29 ± 10.4 to 39 ± 12.4%	109 ± 71 to 69 ± 42 ml/m^2(p < 0.005)	89.2% (18-months)	N
Mickleborough (2004)[11] (n=285)	2.8%	10% (p<.000)	1.3 classes/ patient for 140 patients	82%	62%
Sartipy (2005)[13] SVR via Dor procedure for Class III or IV HF (n=101)	7.9% (early-mortality) measured, within 30 days	6%		65%	
Bolooki (2003)[12] SVR for Class III or IV HF	16%	9%		53%	30%
	Hospitals Included	**Years Included**	**In-Hospital Mortality**	**Combined Death or Major Complications**	
Hernandez (2006)[14] SVR (n=731)	141	2002-2004	9.3%	33.5%	
Yang (2023)[16]	**In-hospital mortality**	**Improvement in LVEFmeasured by TTE**	**Rehospitalizations forCHF**	**Cumulative CV event-free survival rate**	
SVR+CABG(n=70)	1.4%	35.9%±8.4% to 48.1%±8.9% (p<0.001)	4.3%	87%	

NYHA: New York Heart Association; SVR: surgical ventricular restoration; RMA: restrictive mitral annuloplasty; ELIET: endocardial linear infarct exclusion technique; CI: confidence interval; Diff: difference; HR: hazard ratio; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk.

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 had 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 MI during the period of January 1998 to July 2000.[10] 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% 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 outcomes improved in younger patients, those with higher ejection fractions and those not needing mitral valve replacement.[11]

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.[12] 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% from 24% (p<0.000) and symptom class in 140 patients improved 1.3 functional class per patient. Patients were followed up for up to 19 years (mean, 63), 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 congestive heart failure, angina, ventricular tachyarrhythmia, or MI using 3 operative methods during the period of 1979 to 2000.[13] 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%. Mean preoperative ejection fraction was 28%. 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.[14] 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% to 33% postoperatively. Patients were followed up 4.4 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.[15] 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.[14] Improvement in a number of clinical variables was noted, including decreased left-ventricular dyssynchrony, reduced tricuspid regurgitation, and improved ejection fraction (27%–36%).

Yang et al (2023) reported on long-term outcomes after CABG with or without SVR in patients with severe left ventricular dysfunction from 2010 to 2022.[16] A total of 140 patients were included in the analysis (n=70 for each of the SVR+CABG and CABG groups), and the average follow-up duration was 123.1 months (range, 102 to 140 months). Patients in the SVR+CABG group had fewer rehospitalizations for congestive heart failure compared to the CABG group (4.3% vs. 19.1%; p=0.007), but there was no difference in mortality rate between the groups (2.9% vs. 4.4%, p=0.987). Patients in the SVR+CABG group also had greater improvement in terms of LVEF/left ventricular end-diastolic diameter and NYHA class compared to the CABG group.

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 on 33 patients with class III/IV heart failure that underwent SVR and/or restrictive mitral annuloplasty.[17] Operative mortality was 3%, and additional in-hospital mortality was 9%. QOL scores improved as did 6-minute walking distance (248 to 422 meters). Williams et al (2007) 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.[18] 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 (68%) versus class II or III disease (88%). 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.[19] 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. 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%).[20] Operative mortality was 11%. Patients demonstrated improvements in ejection fraction as well as end-systolic LV volume index after the procedure.

SUMMARY OF EVIDENCE

For individuals who have ischemic dilated cardiomyopathy who receive surgical ventricular restoration (SVR) as an adjunct to coronary artery bypass grafting, the evidence includes a large randomized controlled trial (RCT) (another RCT reported results, but most of the patients were included in the larger trial) and a number of uncontrolled studies. Relevant outcomes are overall survival, symptom, quality of life, hospitalizations, resource utilization, and treatment-related morbidity. The RCT, the Surgical Treatment of Ischemic Heart Failure (STICH) trial, did not report significant improvements in quality of life outcomes for patients undergoing SVR in addition to standard coronary artery bypass grafting 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

The purpose of the Supplemental Information is to provide reference material regarding clinical input, existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement or that the information is used in the evidence review.

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association for Thoracic Surgery

The American Association for Thoracic Surgery published an expert consensus document on coronary artery bypass grafting (CABG) in patients with ischemic cardiomyopathy and heart failure in 2021.[22] The document notes that tenets of surgical ventricular restoration (SVR) at the time of CABG that may "confer the most benefit to patients include resection of scarred myocardium, reducing ventricular size, and restoring an anatomically elliptical shape";

however, the document notes that "it remains uncertain which patients should receive [SVR] as part of the CABG operation and what the impact is on long-term survival and functional outcome." The American Association for Thoracic Surgery does state that "concomitant SVR should be considered for patients with a true left ventricular aneurysm" (class of recommendation: IIa; level of evidence: B-R).

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04489355	Assessment of Risks and Outcomes of Surgical Intervention in Patients with Ischemic Cardiomyopathy in the Early and Long-Term Postoperative Period, Selection of Optimal Surgical Treatment	260	May 2024
NCT04331769	Randomized Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients Who Present With Symptomatic Heart Failure With Reduced Ejection Fraction (HFrEF): The CORCINCH-HF Study	400	Dec 2027
NCT03183895[a]	Safety and Performance Evaluation of the AccuCinch® Ventricular Repair System for the Treatment of Heart Failure With or Without Functional Mitral Regurgitation Due to Dilated Ischemic or Non-Ischemic Cardiomyopathy - The CorCinch-EU Study	132	Dec 2027

Government Regulations

National:

There is no national coverage determination addressing surgical ventricular restoration. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Local:

There is no local coverage determination on this topic. There is a fee for procedure code 33548.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid, [formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Cardiac Support Devices
- Partial Left Ventriculectomy

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/06	7/15/06	7/14/06	Joint policy established
11/1/07	8/21/07	10/30/07	Routine maintenance
11/1/09	8/18/09	8/18/09	Routine maintenance

9/1/12	6/12/12	6/19/12	Routine update. References added. Reformatted to mirror BCBSA policy.
7/1/14	4/10/14	4/15/14	Routine maintenance
9/1/15	6/19/15	7/16/15	Routine maintenance. No change in policy status.
9/1/16	6/21/16	6/21/16	Routine maintenance. Updated references and rationale. No change in policy status.
9/1/17	6/20/17	6/20/17	Routine maintenance. Updated references. No change in policy status.
9/1/18	6/19/18	6/19/18	Routine policy maintenance. Updated rationale, added references 6 and 19. No change in policy status.
9/1/19	6/18/19		Routine policy maintenance, no change in policy status.
9/1/20	6/16/20		Routine policy maintenance, no change in policy status.
9/1/21	6/15/21		Routine policy maintenance, no change in policy status.
9/1/22	6/21/22		Routine policy maintenance, no change in policy status, reference #20 replaced.
9/1/23	6/13/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
9/1/24	6/11/24		Routine policy maintenance, updated rationale section, added reference #16. No change in policy status. Vendor managed: N/A (ds)

Next Review Date: 2nd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SURGICAL VENTRICULAR RESTORATION (SVR)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.