7.01.103	Surgical Ventricular Restoration		
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Section:	7.0 Surgery	**Page:**	Page 1 of 16

Policy Statement

I. Surgical ventricular restoration (SVR) is considered **investigational** for the treatment of ischemic dilated cardiomyopathy.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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.

Coding

See the Codes table for details.

Description

Surgical ventricular restoration is 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 ischemic dilated cardiomyopathy.

Summary of Evidence

For individuals who have ischemic dilated cardiomyopathy who receive surgical ventricular restoration (SVR) as an adjunct to coronary artery bypass grafting (CABG) , the evidence includes a large randomized controlled trial (RCT) (another RCT 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 RCT, 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 that the technology results in an improvement in the net health outcome.

Related Policies

- N/A

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]) prohibits 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.

Regulatory Status

he U.S. Food and Drug Administration (FDA) regulates the marketing of devices used as intracardiac patches through the 510(k) clearance process. These devices are Class II and are identified as apolypropylene, polyethylene terephthalate, or polytetrafluoroethylene patch or pledget placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures. Biological tissue may also be a component of the patches. In 2004, the CorRestore™ Patch System (Somanetics; acquired by Medtronic) was cleared for marketing by the FDA 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. FDA 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. In 2022, the FDA granted Breakthrough Device Designation to the AccuCinch® ventricular restoration system.

Rationale

Background

Surgical Ventricular Restoration

Surgical ventricular restoration (SVR) is also known as surgical anterior ventricular endocardial restoration, left ventricular reconstructive surgery, endoventricular circular plasty, or the Dor procedure. Named after the surgeon who pioneered the expansion of techniques for ventricular reconstruction and is credited with treating heart failure patients with SVR and coronary artery bypass grafting.

Surgical ventricular restoration is usually performed after coronary artery bypass grafting 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 (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 evidence review 7.01.66), which does not attempt specifically to resect akinetic segments and restore ventricular contour.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 (RCT) 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Surgical Ventricular Restoration

Clinical Context and Therapy Purpose

The purpose of surgical ventricular restoration (SVR) as an adjunct to standard coronary artery bypass grafting (CABG) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as CABG alone, in individuals with ischemic dilated cardiomyopathy. The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is 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, quality of life, 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 1 outcome of interest, longer follow-up is 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:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

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

Review of Evidence

Randomized Controlled Trials

In 2002, the international 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 (Tables 1 and 2).[1,] This unblinded trial was performed at 127 clinical sites in 26 countries. The STICH trial tested 2 hypotheses, examining the effect of (1) medical therapy versus medical therapy plus CABG and (2) medical therapy plus CABG versus 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) (Table 2). The primary outcome was a composite of death from any cause and hospitalization for cardiac reasons.

Table 1. Summary of Key Randomized Controlled Trial 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 to 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; STICH: Surgical Treatment of Ischemic Heart Failure; SVR: surgical ventricular restoration.
[a] Key eligibility criteria.

Table 2. Summary of Key Randomized Controlled Trial 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	.98	.73	.82	.88	.96	.35

Values are n (%) unless otherwise indicated.
CABG: coronary artery bypass grafting; CI: confidence interval; HR: hazard ratio; ITT: intention to treat; MI: myocardial infarction; SVR: surgical ventricular restoration.

The purpose of the gaps tables (Tables 3 and 4) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 3. Study 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% to 12%); much higher than the 1% mortality reported in 1978 of 1000 patients from the Cleveland Clinic	

STICH: Surgical Treatment of Ischemic Heart Failure
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps 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. Clinical significant difference not prespecified; 6. Clinical 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			

STICH: Surgical Treatment of Ischemic Heart Failure
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps 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 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.[2,] 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=.36) or mortality plus cardiac hospitalization (p=.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.[3,4,] 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.[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=.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. In 2018, a subgroup analysis investigated the association of sex (gender) and the long-term benefit of CABG plus medical therapy versus medical therapy on all-cause mortality, cardiovascular mortality, the composite of death or hospitalization, or surgical deaths in the STICH cohort to compare for gender-related interactions.[7,] The analyses found no association between sex and outcomes, recommending that gender should not influence CABG treatment decisions.

A separate 2009 publication from the STICH trial reported on quality of life outcomes.[8,] The main quality of life 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 quality of life. Secondary quality of life 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 quality of life 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 quality of life measures.

A second RCT was published by Marchenko et al. (2011).[9,] 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=not significant). 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.

Nonrandomized Trials

Tables 5 and 6, below, summarize the characteristics and results of key nonrandomized trials and observational studies. The studies range in size (range n, 101 to 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) [10,]	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-years
Athanasuleas (2001) [11,]	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-months
Mickleborough (2004)[12,]	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 years; mean 63 months
Bolooki (2003)[13,]	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)	Ventriculotomy closure+intracavitary oval patch (n=22)		≤22 years

Study	Study Type	Country	Dates	Participants	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Follow-Up
Sartipy (2005)[14,]	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-years
Hernandez (2006)[15,]	Comparative Study	US	2002-2004	Patient data from the Society of Thoracic Surgeons' database	SVR procedure (n=731)				
Yang (2023)[16,]	Cohort	China	2010-2022	who underwent CABG and SVR or isolated CABG for chronic MI and severe LV dysfunction	SVR+CABG (n= 70)	CABG (n= 70)			≤12 years
Hamid (2023)[17,]	Cohort	US, Europe	2016-2021	Patients with HFrEF.who underwent SVR therapy with the AccuCinch TLVR system	SVR (n=51)				12 months

CABG: coronary artery bypass grafting; HFrEF: Heart failure with reduced ejection fraction; LV: left ventricular;MI: myocardial infarction;NR: not reported; SVR: surgical ventricular restoration; TLVR: Transcatheter Left Ventricular Restoration.

Table 6. Summary of Key Nonrandomized Trials Study Results

Study	In-Hospital Mortality	Increase in post-operative ejection fraction	Decrease in left ventricular end systolic volume index	Survival rate (post-op year)	Freedom from hospitalization
Athanasuleas (2001)[10,](n=662)	7.7%	10.3% (p<.05)		89.4% (3)	88.7% (3)
Athanasuleas (2001)[11,](n=439)	6.6%	29 ± 10.4 to 39 ± 12.4%	109 ± 71 to 69 ± 42 ml/m^2 (p<.005)	89.2% (18-months)	
	In-hospital mortality	**Increase in post-operative ejection fraction**	**Symptom-class improvement**	**Survival rate (post-op year 5)**	**Survival rate (post-op year 10)**
Mickleborough (2004)[12,]					

Study	In-Hospital Mortality	Increase in post-operative ejection fraction	Decrease in left ventricular end systolic volume index	Survival rate (post-op year)	Freedom from hospitalization
Total (n=285)	2.8%	10% (p<.000)	1.3 classes/patient for 140 patients	82%	62%
Sartipy (2005)[14,]					
SVR via Dor procedure for Class III or IV HF (n=101)	7.9% (early mortality) measured within 30 days	6%	-	65%	-
Bolooki (2003)[13,]					
SVR for class III or IV HF (n=157)	16%	9%		53%	30%
	Hospitals included	**Years included**	**In-hospital mortality**	**Combined death or major complications**	
Hernandez (2006)[15,]					
SVR (n=731)	141	2002 to 2004	9.3%	33.5%	
	In-hospital mortality	**Improvement in LVEF measured by TTE**	**Rehospitalizations for CHF**	**Cumulative CV event-free survival rate**	
Yang (2023)[16,]					
SVR+CABG (n=70)	1.4%	35.9%±8.4% to 48.1%±8.9% (p<0.001)	4.3%	87%	
	Change in end-diastolic volume at 12 months	**Change in end-systolic volume at 12 months**	**KCCQ score**	**6MWT**	
Hamid (2023)[17,]					
SVR (n=51)	-33.6 +/- 34.8 mL (95% CI, -44.6 to -22.6; p<.01)	-28.5 +/- 28.2 (95% CI, -37.4 to -19.6; p<.01)	16.4 +/- 18.7 points (95% CI, 10.9 to 21.9; p<.01)	45.9 +/- 83.9 m (95% CI, 20.4 to 71.4 ; p<.01)	

6MWT: 6-miute walk test; CI: confidence interval; CV: cardiovascularHF: heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LVEF: left ventricular ejection fraction; SVR: surgical ventricular restoration; TTE: Transthoracic echocardiogram

The Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the Left Ventricle (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.[10,] In addition to SVR, patients 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% to 40.0% (p<.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. (2001) reported that 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 concomitantly underwent CABG (93%), patch septoplasty (22%), arrhythmia ablation (41%), mitral repair (3%), and mitral replacement (3%). Surgical ventricular restoration was performed on the beating heart in 7% of patients. The authors reported a hospital mortality of 2.8%; postoperative ejection fractions increased 10% from 24% (p<.0001), 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 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.[13,] Surgical ventricular restoration 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 a hospital mortality of 16%. Mean preoperative ejection fraction was 28%. Patients were followed for up to 22 years, and overall 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 an 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.[14,] 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 a median of 4.4 years, and overall 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.[15,] 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% of patients. 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.[18,] Improvement in a number of clinical variables was noted, including decreased left ventricular dyssynchrony, reduced tricuspid regurgitation, and improved ejection fraction (27% to 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.

Hamid et al (2023) reported on a retrospective analysis on the clinical outcomes of the AccuCinch Transcatheter Left Ventricular Restoration system. [17,] The primary endpoint was the change in LV end-diastolic volume at 12 months compared to baseline. Among the 51 patients, at 12 months, the LV end-diastolic volume decreased by 33.6 mL on average (p<.01), accompanied by similar reductions in end-systolic volume. These changes were linked to significant improvements in quality of life (16.4-point increase on the Kansas City Cardiomyopathy Questionnaire) and exercise capacity (45.9 m increase in the 6-minute walk test). There were no periprocedural deaths, though one patient died on day 280 and another required a ventricular assist device on day 13.

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.[19,] Operative mortality was 3%, and additional in-hospital mortality was 9%. Quality of life scores improved, as did 6-minute walking distance (248 to 422 meters). Williams et al. (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.[20,] 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%) versus 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%.[21,] 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%).[22,] Operative mortality was 11%. Patients demonstrated improvements in ejection fraction as well as end-systolic left ventricular volume index after the procedure.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statement

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.[23,] 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).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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
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
NCT04331769[a]	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 2030

[a]Denotes industry-sponsored or cosponsored trial

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, Dor procedures)
HCPCS	None	

Policy History

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

Effective Date	Action
11/26/2014	BCBSA Medical Policy Adoption
04/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
04/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
04/01/2021	Annual review. No change to policy statement. Literature review updated.
04/01/2022	Annual review. No change to policy statement. Literature review updated.
04/01/2023	Annual review. No change to policy statement. Literature review updated.
04/01/2024	Annual review. No change to policy statement. Literature review updated.
04/01/2025	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

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 and Feedback (as applicable to your plan)

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 be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Surgical Ventricular Restoration 2.04.08 **Policy Statement:** I. Surgical ventricular restoration (SVR) is considered **investigational** for the treatment of ischemic dilated cardiomyopathy.	**Surgical Ventricular Restoration 2.04.08** **Policy Statement:** I. Surgical ventricular restoration (SVR) is considered **investigational** for the treatment of ischemic dilated cardiomyopathy.