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Cardiac Restoration and Remodeling Procedures

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Coverage

For the purposes of this policy, cardiac restoration and remodeling procedures include surgical ventricular restoration (SVR) and partial left ventriculectomy (PLV).

Surgical Ventricular Restoration (SVR)
Surgical ventricular restoration **is considered experimental, investigational and/or unproven** for individuals with akinetic segments of the heart caused by the following indications, including but not limited to:

1. Ischemic dilated cardiomyopathy,
2. Post-infarction left ventricular aneurysm,
3. Congestive heart failure (CHF),
4. Coronary artery disease (CAD),
5. Coronary valve insufficiency or stenosis, or
6. Any other coronary etiology.

Partial Left Ventriculectomy (PLV)

Partial left ventriculectomy **is considered experimental, investigational and/or unproven** for all indications.

EXCEPTION: Ventricular aneurysmectomy (ventricular aneurysm repair) may be done with or without SVR or PLV in individuals undergoing a coronary artery bypass graft (CABG) for severe unresponsive CHF and ejection fraction (EF) equal to or less than 30%.

Policy Guidelines

Surgical ventricular restoration (SVR) 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.

Partial left ventriculectomy (PLV; also known as the Batista procedure) should be reported using CPT code 33999. CPT codes 33542 and 33548 should not be used to bill for PLV.

Description

For the purposes of this policy, cardiac restoration and remodeling procedures include surgical ventricular restoration (SVR) and partial left ventriculectomy (PLV).

Background

Surgical Ventricular Restoration (SVR)

SVR is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in patients with akinetic (lack of muscle movement) segments of the heart, secondary to ischemic dilated cardiomyopathy.

SVR is also known as surgical anterior ventricular endocardial restoration (SAVER), left ventricular reconstructive surgery, endoventricular circular patch plasty (EVCPP), or the Dor procedure (named after Vincent Dor, MD). Dr. Dor pioneered the expansion of techniques for ventricular reconstruction (VR) and is credited with treating heart failure patients with SVR and coronary artery bypass grafting (CABG).

The SVR procedure 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 (VT). 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 (PLV) (discussed below), which does not attempt specifically to resect akinetic segments and restore ventricular contour.

Partial Left Ventriculectomy (PLV)

PLV is a surgical procedure aimed at improving the hemodynamic status of patients with end-stage (irreversible) congestive heart failure (CHF) by directly reducing left ventricular size, and thereby improving the pump function of the left ventricle. This is accomplished by reducing cardiac volume and left ventricular wall tension through resection of the posterolateral wall of the left ventricle. This surgical approach to the treatment of CHF (also known as the Batista procedure, cardio-reduction, or left ventricular remodeling surgery) is primarily directed at patients with an underlying non-ischemic dilated cardiomyopathy awaiting cardiac transplantation. PLV has been investigated as a "bridge" to transplantation or as an alternative to transplantation. The theoretical rationale for this procedure is that by reducing left ventricular wall volume, left ventricle wall tension is reduced and left ventricle pumping function will be improved.

Treatment of heart failure is generally through lifestyle modifications and medications. Medications are effective for controlling the symptoms of heart failure, but progression of disease can still occur. For end-stage heart failure, consideration of cardiac transplantation is the main alternative.

The original PLV procedure, developed by Batista, involves a wide excision of the posterolateral wall and apex of the heart and removal of a wedge-shaped portion of the left ventricle. PLV may be accompanied by repair of the mitral valve, either through valvuloplasty or annuloplasty. A variety of complications of PLV have been reported, including sudden death, progressive heart failure, arrhythmias, bleeding, renal failure, respiratory failure, and infection. More recently, modifications have been suggested that remove the septal-anterior wall preferentially, also called anterior PLV. The decision on the optimal approach may be determined by the degree of fibrosis seen in the apex and lateral walls.

Regulatory Status

Surgical Ventricular Restoration (SVR)

The 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 polypropylene, 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.

Partial Left Ventriculectomy (PLV)
PLV is a surgical procedure and, as such, is not subject to regulation by the FDA.

Rationale

The policy for partial left ventriculectomy was created in 1999. This policy has been regularly updated with peer-reviewed scientific literature searches of the PubMed database through January 8, 2024.

Medical policies 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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 (SVR)
Clinical Context and Therapy Purpose
The purpose of 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 policy.

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 one 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.

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 (HF) and coronary heart disease (CHD) (NCT00023595). This trial was sponsored by the National Heart, Lung, and Blood Institute (NHLBI). Results of the STICH trial was published in 2009 (Tables 1 and 2). (1) 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 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 (CAD) 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 RCT Characteristics

					Interventions	
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 years	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**	**HOSP for Cardiac Causes**	**HOSP 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; HOSP: hospitalization; HR: hazard ratio; ITT: intention-to-treat; MI: myocardial infarction; NR: not reported; RCT: randomized controlled trial; 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%–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 (MI), 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 (SPECT) 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 (LVEF), 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=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. In 2018, a subgroup analysis investigated the association of sex (gender) and the long-term benefit of CABG plus medical therapy vs. 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 (QOL) outcomes. (8) The main QOL outcome measurement tool used was the Kansas City Cardiomyopathy Questionnaire (KCCQ), which is a 23-item scale that assesses the effect of HF 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 with the CABG alone group. Similarly, there were no group differences noted on any of the secondary QOL 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 [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 and angina classes for both groups after surgery, but between-group statistical testing was not reported. For example, mean NYHA 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 5A, 5B, and 6 below summarize the characteristics and results of key nonrandomized trials and observational studies (n=6), including five cohort studies and one review comparing SVR to other surgical interventions in multiple populations. 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 5A. Summary of Key Nonrandomized Trial Characteristics

Study	Study Type	Country	Dates	Participants
Athanasuleas et al. (2001) (10)	Cohort	US, Monaco, Italy	1998-2000	who underwent SVR after anterior myocardial infarction with or without concomitant procedures (n=662)
Athanasuleas et al. (2001) (11)	Cohort	US, Monaco, Italy	1998-1999	who underwent SVR after anterior myocardial infarction with or without concomitant procedures (n=439)

Mickleborough et al. (2004) (12)	Cohort	Canada	1983-2002	who underwent SVR for Class III or IV heart failure, angina, or ventricular tachyarrhythmia with or without concomitant procedures (n=285)
Bolooki et al. (2003) (13)	Cohort	US	1997-2000	who underwent SVR for Class III or IV heart failure, angina, ventricular tachyarrhythmia, or myocardial infarction (n=157)
Sartipy et al. (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)
Hernandez et al. (2006) (15)	Comparative Study	US	2002-2004	Patient data from the Society of Thoracic Surgeons' database
Yang et al. (2023) (16)	Cohort	China	2010-2022	who underwent CABG and SVR or isolated CABG for chronic MI and severe LV dysfunction

CABG: coronary artery bypass grafting; LV: left ventricular; MI: myocardial infarction; NR: not reported; SVR: surgical ventricular restoration; US: United States.

Table 5B. Summary of Key Nonrandomized Trial Characteristics (continued)

Study	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Follow Up
Athanasuleas et al. (2001) (10)	SVR+CABG (n=609)	SVR+Mitral Repair (n=146)	SVR+Mitral Replacement (n=20)		3 years
Athanasuleas et al. (2001) (11)	SVR+CABG (n=391)	SVR+Mitral Repair (n=97)	SVR+Mitral Replacement (n=18)		18 months
Mickleborough et al. (2004) (12)	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 et al. (2003) (13)	Radical aneurysm resection+ linear closure (n=65)	Septal dyskinesia reinforced with patch septoplasty (n=70)	Ventriculotomy closure+intracavitary oval patch (n=22)		≤22 years
Sartipy et al. (2005) (14)	SVR+CABG (n=99)	SVR+arrythmia ablation (n=53)	SVR+mitral valve procedure (n=29)		5 years

Hernandez et al. (2006) (15)	SVR procedure (n=731)				
Yang et al. (2023) (16)	SVR+CABG (n= 70)	CABG (n=70)			≤12 years

CABG: coronary artery bypass grafting; LV: left ventricular; MI: myocardial infarction; NR: not reported; SVR: surgical ventricular restoration; CABG: coronary artery bypass graft.

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 et al. (2001) (10) (n=662)	7.7%	10.3% ($p<0.05$)		89.4% (3)	88.7% (3)
Athanasuleas et al. (2001) (11) (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)	
	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 et al. (2004) (12)					
Total (n=285)	2.8%	10% (p<.000)	1.3 classes/ patient for 140 patients	82%	62%
Sartipy et al. (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 et al. (2003) (13)					
SVR for class II of IV HF (n=157)	16%	9%		53%	30%
	Hospitals included	**Years included**	**In-hospital mortality**	**Combine death or**	

				major complications	
Hernandez et al. (2006) (15)					
SVR (n=731)	141	2002-2004	9.3%	33.5%	
	In-hospital mortality	**Improvement in LVEF measured by TTE**	**Re-hospitalizations for CHF**	**Cumulative CV event-free survival rate**	
Yang et al. (2023) (16)					
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; CV: cardiovascular; Diff: difference; HR: hazard ratio; HF: heart failure; LVEF: left ventricular ejection fraction; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk; SVR: surgical ventricular restoration: TTE: Transthoracic echocardiogram.

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 MI 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% ($p<0.05$). The survival rate and freedom from hospitalization for HF 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 HF, 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%). SVR 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% ($p<0.0001$), 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 HF, angina, ventricular tachyarrhythmia, or MI using 3 surgical methods from 1979 to 2000. (13) 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 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 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 HF, 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%; LVEF 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. (17) 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.

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 HF who underwent SVR and/or restrictive mitral annuloplasty. (18) 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) retrospectively reviewed outcomes following SVR in a series of 34 patients with NYHA class IV HF and 44 patients with class II or III HF who had surgery between 2002 and 2005. (19) 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 CAD who underwent CABG or CABG plus SVR reported an ejection fraction of 30% to 40%. (20) 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%). (21) Operative mortality was 11%. Patients demonstrated improvements in ejection fraction as well as end-systolic LV volume index after the procedure.

Ongoing and Unpublished Clinical Trials

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

Table 7. Summary of Key Trials

NCT Number	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	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.

Practice Guidelines and Position Statements

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).

Summary of Evidence: Surgical Ventricular Restoration (SVR)

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 (STICH) 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.

Partial Left Ventriculectomy (PLV)

Results from an international registry of patients undergoing LV volume reduction surgery were published in 2005. (23) This publication reported on 568 patients from 12 countries in North America, Europe and Asia, including patients with non-ischemic cardiomyopathy undergoing PLV, as well as patients with ischemic cardiomyopathy undergoing SVR. The number of procedures peaked in the years 1997-2000 and has subsequently declined since that time. The largest decline has been in North America and Europe, where few of these procedures have been performed since 2001. Of the 568 patients enrolled in the registry, 271 (47.7%) died or were lost to follow-up. The main causes of death were progressive heart failure (48.4%), sudden death (10.3%), and arrhythmias (6.6%).

Case Series

Suma et al. treated 95 patients with idiopathic dilated cardiomyopathy between 1999 and 2006. (24) A total of 57 of 95 (60%) underwent PLV with excision of the lateral wall, and 38 of 95 (40%) underwent a septal anterior ventricular exclusion (SAVE) procedure with excision of the anteroseptal wall. Hospital mortality was 11.6% (11/95), and 1-, 3-, and 5-year survival was 72.8%, 61.4%, and 50.5%, respectively. LV ejection fraction improved from 22.3% pre-surgery to 27.2% post-surgery ($p<0.001$), and cardiac index improved from 2.3±0.5 to 2.8+0.5 m^2/min. There was an improvement in mean NYHA class from 3.5 to 1.7. The lack of a control group in this trial makes it difficult to determine the impact of PLV on clinical outcomes.

Franco-Cereceda et al. reported on the 1- and 3-year outcomes of 62 patients with dilated cardiomyopathy who underwent PLV. (25) At the time of surgery, all patients were either in NYHA functional class III or IV. Survival was 80% and 60% at 1 and 3 years after surgery, and freedom from heart failure was 49% and 26%, all respectively. Although 80% of the patients were alive at 1 year, this survival was achieved with the aggressive use of ventricular assistive

devices (VADs) and transplantation as a salvage therapy. The authors concluded that PLV is not a predictable reliable alternative to transplantation.

Starling et al. treated 59 patients with dilated cardiomyopathy and advanced heart failure with PLV and mitral valve repair. (26) Hospital mortality was 3.5%, and actuarial survival at 1 year was 82%. Freedom from treatment failure (defined as death or relisting for transplantation) was 58% at 1 year. In patients with event-free survival at 12 months, there were improvements in NYHA class (3.6 to 2.1, $p<0.001$), LV ejection fraction (13 to 24%, $p<0.001$), and peak oxygen consumption (10.8-16.0 mL/kg/min). However, worsening of heart failure was common among survivors over time, and the 3-year estimate of freedom from death, LV assist device, transplantation, or worsening heart failure, was only 26%. Starling noted that although PLV is able to reduce left ventricular volume and probably decreases ventricular wall stress, deduction of volume and stress is insufficient to improve ventricular function.

Sugiyama et al. reported on 11 children under the age of 3 years diagnosed with severe dilated cardiomyopathy. (27) Eight procedures were done on 6 of the children: 5 PLVs and 3 mitral valve replacements. Two of them underwent mitral valve replacement after PLV. Follow up after PLV ranged from 2 months to 8 years. During the follow up period, 4 patients remained alive, of whom 1 eventually underwent a heart transplant.

In 2009, Nishina et al. reported on a study that aimed to investigate the effectiveness of an apex sparing PLV compared to conventional PLV to restore the ellipsoidal shape of the left ventricle in 13 patients with dilated cardiomyopathy. (28) The authors reported left ventricular function improvement as the ejection fraction increased from 28% to 39% and the NYHA class improved from III to I. Survival rates were not reported in this small study.

In 2015, a systematic review of PLV cases over the last 12 years was conducted by Domingues et al. (29) The authors reported the following, “There has been a considerable number of reported successful cases and highly significant findings in regard to determining the most suitable region for the section [of the ventricular wall], proper selection of the patients indicated for the procedure, including the influence of the coronary artery anatomy in the nomination procedure, and the need for preservation of ventricular geometry to ensure better quality of ventricular contractions after the sectioning. This surgical procedure has been successfully performed, mainly in Japan; improvements in its efficiency were found, and the need for a mathematical modeling of the slice to be severed is a prominent factor in many studies.”

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in September 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Practice Guidelines and Position Statements

American College of Cardiology/American Heart Association (ACC/AHA)

The 2005 ACC/AHA Guideline for the Diagnosis and Management of Chronic Heart Failure in the Adult (updated in 2009) addressed PLV. The guidelines included the following as a Class III recommendation, "Partial left ventriculectomy is not recommended in patients with non-ischemic cardiomyopathy and refractory end-stage heart failure. (Level of Evidence: C)" (30) As of July 17, 2018, there is no longer an ACC/AHA guideline addressing PLV.

Society of Thoracic Surgeons (STS)
In 1997, the STS issued a policy statement recommending that PLV be considered an investigational procedure and that it should not be used as a primary strategy for the management of end-stage congestive heart failure. (31) As of July 17, 2018, there is no longer an STS guideline addressing PLV.

Summary of Evidence: Partial Left Ventriculectomy (PLV)

For individuals who have end-stage congestive heart failure (HF) who receive a partial left ventriculectomy (PLV), the evidence includes several case series. Relevant outcomes are overall survival, symptoms, quality of life, hospitalizations, resource utilization, and treatment-related morbidity. Over the years, some clinical series have reported improvement in ejection fraction and symptoms following PLV; however, there is a lack of randomized controlled trials (RCT) comparing this procedure to alternative treatments. Perioperative mortality and complications are high, and the improvements reported in symptoms may not be a result of the surgical procedure. The high rates of perioperative morbidity and mortality, the lack of demonstrated long-term outcome benefits, and the high relapse rates have led to diminished enthusiasm for this procedure. Additionally, there are no longer any professional guidelines or position statements that address the PLV procedure. Additionally, there are no longer any professional guidelines or position statements that address the PLV procedure.

Additionally, there are no longer any professional guidelines or position statements that address the PLV procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	33542, 33548, 33999
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Document updated with literature review. Coverage unchanged. Reference 16 added.
08/15/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. Coverage unchanged. References 7 and 21 added, others removed.
06/15/2021	Reviewed. No changes.
09/15/2020	Document updated with literature review. Coverage unchanged. Reference 20 added, and one reference removed.
10/15/2019	Reviewed. No changes.
10/01/2018	Document updated with literature review. Coverage unchanged. Reference 6 and 19 added.
07/15/2017	Reviewed. No changes.
07/15/2016	Document updated with literature review. Coverage unchanged.

11/01/2015	Reviewed. No changes.
04/15/2014	Document updated with literature review. Coverage unchanged.
03/01/2013	Document updated with literature review. Coverage remains unchanged. This medical document is no longer scheduled for routine literature review and update.
11/15/2010	Document updated with literature review. The following changes were made: 1) Partial Left Ventriculectomy (PLV) was combined into this document; PLV was previously addressed on SUR707.019, Partial Left Ventriculectomy. Coverage of PLV is unchanged. 2) Coverage of Surgical Ventricular Restoration is unchanged. 3) The following exception was added to Coverage section: Ventricular aneurysmectomy (ventricular aneurysm repair) may be done with or without SVR or PLV in patients undergoing coronary artery bypass grafting for severe unresponsive congestive heart failure and ejection fraction of equal to or greater than 30%. 4) Document title changed from Surgical Ventricular Restoration. Document title change to "Cardiac Restoration and Remodeling Procedures".
10/01/2008	Revised/updated entire document
05/01/2006	Revised/updated entire document
01/01/2006	New medical document Partial Left Ventriculectomy