I. POLICY

Partial Left Ventriculectomy

Partial left ventriculectomy is considered **not medically necessary**.

Surgical Ventricular Restoration

Surgical ventricular restoration is considered **investigational** for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

_Cross-reference:_
MP-1.026 Ventricular Assist Devices and Artificial Hearts

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids [N] Indemnity
[N] PPO [N] SpecialCare
[N] HMO [N] POS
[N] SeniorBlue PPO [Y] FEP PPO*
[N] SeniorBlue HMO

*Refer to FEP Medical Policy Manual MP-7.01.103 Surgical Ventricular Restoration.. The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)
III. DESCRIPTION/BACKGROUND

Partial Left Ventriculectomy

Partial left ventriculectomy (PLV) is a surgical procedure aimed at improving the hemodynamic status of patients with end-stage congestive heart failure (CHF) by directly reducing left ventricular size, and thereby improving the pump function of the left ventricle (LV).

This surgical approach to the treatment of congestive heart failure (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. Initially, the procedure was intended for patients awaiting cardiac transplantation, either 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, LV wall tension is reduced and left ventricle (LV) 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. Ventricular assist devices (VADs) have been tested for this purpose, and total artificial hearts are also in development.

The original partial left ventriculectomy (PLV) procedure, as 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 LV. 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.

Surgical Ventricular Restoration

Surgical ventricular restoration (SVR) is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in patients with akinetic segments of the heart, secondary to either dilated cardiomyopathy or post-infarction left ventricular aneurysm.

The surgical ventricular restoration (SVR) procedure may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER), left ventricular
reconstructive surgery, left ventricular aneurysmectomy reconstruction, endoventricular circular plasty, or the Dor procedure named after Vincent Dor, MD. Dr. Dor pioneered the expansion of techniques for ventricular reconstruction and is credited with treating heart failure patients with SVR in conjunction with coronary artery bypass grafting (CABG).

The SVR procedure is usually performed after CABG and may proceed or be followed by mitral valve repair or replacement and other procedures such as endocardectomy and cryoablation for treatment of ventricular tachycardia. A key difference between SVR and ventriculectomy (i.e., for aneurysm removal) is that in SVR, circular “purse string” suturing is used around the border of the aneurysmal scar tissue. Tightening of this suture is believed to isolate the akinetic or dyskinetic scar, bring the healthy portion of the ventricular walls together, and restore a more normal ventricular contour. If the defect is large (i.e., an opening >3 cm), the ventricle may also be reconstructed using patches of autologous or artificial material to maintain the desired ventricular volume and contour during closure of the ventriculotomy. In addition, SVR is distinct from partial left ventriculectomy (i.e., the Batista procedure, see policy No. 7.01.66), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

The CorRestore™ Patch System is a device approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process that is specifically labeled for use “as an intracardiac patch for cardiac reconstruction and repair.” The device consists of an oval tissue patch made from glutaraldehyde-fixed bovine pericardium. It is identical to other marketed bovine pericardial patches except that it incorporates a suture bolster in the shape of a ring that is used along with ventricular sizing devices, to restore the normal ventricular contour.

IV. RATIONALE

Partial Left Ventriculectomy

This policy is based on a 1998 TEC Assessment, (1) which concluded that the available data were inadequate to permit conclusions regarding health benefits associated with partial left ventriculectomy. Specifically, the Assessment concluded that the lack of any controlled comparison of PLV to medical therapies or other types of “bridge to transplantation” (i.e., ventricular assist devices [VADs]) made scientific assessment of the efficacy of PLV impossible, either in its role as a potential bridge to transplant or as an adjunct to medical therapy.

Since the TEC Assessment was published in 1998, periodic updates of the policy with literature search have been performed. The most recent literature search was during the period of July 2011 through June 2012. There were no controlled trials comparing partial left ventriculectomy (PLV) to alternative treatments identified as part of this search. The available
literature consists of uncontrolled series of patients undergoing PLV and a representative sample of this literature is discussed below.

Results from an international registry of patients undergoing left ventricular (LV) volume reduction surgery were published in 2005. (2) 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 surgical ventricular restoration (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, while use has persisted in Asia. 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%).

Suma et al. (3) treated 95 patients with idiopathic dilated cardiomyopathy between 1999 and 2006. A total of 57/95 (60%) underwent PLV with excision of the lateral wall, and 38/95 (40%) underwent a 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 m²/min. There was an improvement in mean New York Heart Association (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 and colleagues reported on the 1- and 3-year outcomes of 62 patients with dilated cardiomyopathy who underwent partial left ventriculectomy. (4) 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 VADs and transplantation as a salvage therapy. The authors concluded that partial left ventriculectomy is not a predictable reliable alternative to transplantation.

Starling et al. (5) treated 59 patients with dilated cardiomyopathy and advanced heart failure with PLV and mitral valve repair. 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<0.0001), LV ejection fraction (13 to 24%, p<0.0001), 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, left ventricle assist device (LVAD), transplantation, or worsening heart failure, was only 26%.

Summary

Partial left ventriculectomy (PLV) is a surgical procedure aimed at improving the hemodynamic status of patients with end-stage congestive heart failure (CHF) by directly
reducing left ventricular size, and thereby improving the pump function of the left ventricle (LV).

Some clinical series have reported improvement in ejection fraction and symptoms following PLV; however, there is a lack of controlled trials 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. As a result of the lack of evidence on benefits from the procedure, and the possibility of harms, PLV is considered not medically necessary.

**Practice Guidelines and Position Statements**

The American College of Cardiology/American Heart Association (ACC/AHA) Guideline (6) addressed PLV. The ACC guidelines considered PLV as a treatment for heart failure, and included the following as a Class III recommendation:

- Partial left ventriculectomy is not recommended in patients with nonischemic cardiomyopathy and refractory end-stage heart failure.

In 1997, the Society of Thoracic Surgeons 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. (7)

**Surgical Ventricular Restoration**

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 had investigated SVR for the past 20 years in more than 1,000 patients with ischemic cardiomyopathy following anterior infarction. (1-6) While the SVR procedure had been performed for many years, the available data were inadequate to permit conclusions regarding health benefits associated with SVR. Specifically, the lack of any randomized controlled trials (RCTs) comparing SVR to other surgical or medical therapies did not permit scientific assessment of the efficacy of SVR. In addition, patient selection criteria and optimal surgical techniques were still undetermined.

In 2002, a randomized, multicenter international clinical trial on the Surgical Treatment of Ischemic Heart Failure (STICH) was initiated to compare medical therapy with coronary artery bypass grafting (CABG) and/or SVR for patients with heart failure and coronary heart disease ([ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT00023595). The STICH trial was sponsored by the National Heart, Lung, and Blood Institute and was expected to recruit 2,800 patients with
heart failure, left ventricular ejection fraction <0.35, and coronary artery disease amenable to CABG at 50 clinical sites. Patients with extensive anterior ischemia assigned to the surgical arm of the study were to be further randomized to CABG surgery alone versus bypass surgery plus SVR. The 2009 results of this trial, as well as a representative sample of some of the earlier case series on SVR, are discussed below. Literature review updates since 2009, most recently performed for the period of June 2011 through June 2012, focus on controlled trials.

Controlled Trials

In 2006, Ribeiro and colleagues from Brazil reported on 137 patients with anterior myocardial infarction (MI) and ejection fraction less than 50%. (7) Those patients who had viable anterior myocardium were randomized to SVR or SVR plus revascularization, and those patients with nonviable anterior myocardium received SVR. Ejection fraction improved in all groups, but the most improvement was in the SVR plus revascularization group.

Results of the National Heart, Lung, and Blood Institute-sponsored STICH trial were published in 2009. (8) This study was a multicenter, unblinded RCT performed at 127 clinical sites from 26 countries. A total of 1,000 patients with coronary artery disease and ejection fraction of 35% or less were randomized to CABG alone (n=499) or CABG plus SVR (n=501). The primary outcome was a composite of death from any cause and hospitalization for cardiac reasons. While SVR reduced the end-systolic volume index by 19% compared to 6% with CABG alone, there was no difference between groups in the primary outcome, which occurred in 292/499 (59%) of the CABG alone group compared to 289/501 (58%) of the CABG + SVR group (hazard ratio [HR]: 0.99, 95% confidence interval [CI]: 0.84-1.17, p=0.90). Death from any cause occurred in 141/499 (28%) in the CABG alone group compared to 138/501 (28%) in the CABG + SVR group (HR: 1.00, 95% CI: 0.79-1.26, p=0.98). Cardiac symptoms and exercise tolerance also improved to similar degrees between groups. Other secondary outcomes, such as stroke, MI, and subsequent procedures, also did not differ between groups. Subgroup analysis did not reveal any patient groups that benefited from SVR significantly more than the entire group.

A separate publication from the STICH trial reported on quality-of-life (QOL) outcomes. (9) 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 short form (SF)-12, the CES-D depression measure, 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 the CABG alone group. Similarly, there were no group differences noted on any of the secondary QOL measures.
A second RCT was published in 2011 by Marchenko et al. (10) This was a study performed in Russia of 236 patients with ischemic heart failure who were randomized to CABG alone or CABG + SVR. The mean follow-up was 31±13 months. Outcome measures reported were perioperative mortality and survival at 1, 2, and 3 years’ follow-up. Perioperative mortality was 5.8% in the CABG alone group compared with 3.5% in the CABG + SVR group (p=NS, statistical tests not reported). Survival at 1 and 3 years was 95% and 78%, respectively, in the CABG + SVR group, compared with 83% and 78%, respectively, in the CABG alone group (statistical tests not reported). There were reductions in New York Heart Association (NYHA) functional class and angina class for both groups after surgery, but between-group statistical testing was not reported. For example, the NYHA functional class decreased in the CABG + SVR from 3.1±0.4 at baseline to 2.2±0.6 at 3 years, compared with a decrease in the CABG alone group from 2.9±0.5 to 2.4±0.9.

Uncontrolled Studies

Athanasuleas and colleagues 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. (5) 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% ± 11.3% to 40.0% ± 12.3% (p<0.05). The survival rate and freedom from hospitalization for heart failure at 3 years was 89.4% ± 1.3% and 88.7%, respectively. In a separate publication on 439 patients from the RESTORE Group, Athanasuleas and coworkers reported outcomes improved in patients with lower patient age, higher ejection fractions, and lack of need for mitral valve replacement. (6)

Mickleborough and colleagues 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. (11) In addition to SVR, patients also concomitantly underwent CABG (93%), patch septoplasty (22%), arrhythmia ablation (41%), mitral repair (3%), and mitral replacement (3%). SVR was performed on the beating heart in 7% of patients. The authors reported hospital mortality of 2.8%; postoperative ejection fractions increased 10% ± 9% from 24% ± 11% (p<0.000), and symptom class in 140 patients improved 1.3 ± 1.1 functional class per patient. Patients were followed up for up to 19 years (mean, 63 ± 48 months), and overall actuarial survival was reported as 92%, 82%, and 62% at 1, 5, and 10 years, respectively. The authors suggested wall-thinning should be used as a criterion for patient selection.

Bolooki and colleagues reported on 157 patients who underwent SVR by a single surgeon for class III or IV heart failure, angina, ventricular tachyarrhythmia, or MI using 3 operative methods during the period of 1979 to 2000. (12) 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%. The mean preoperative ejection fraction was 28%
+ 0.9%. Patients were followed up for up to 22 years, and overall actuarial survival was reported as 53%, 30%, and 18% at 5, 10, and 15 years, respectively. The authors found factors improving long-term survival included SVR with intraventricular patch repair and ejection fraction of 26% or greater preoperatively.

Sartipy and colleagues reported on 101 patients who underwent SVR using the Dor procedure at a single center for class III or IV heart failure, angina, and ventricular tachyarrhythmia during the period of 1994 to 2004. (13) 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%; left ventricular ejection fraction increased from 27% ± 9.9% to 33% ± 9.3% postoperatively. Patients were followed up 4.4 ± 2.8 years, and overall actuarial survival was reported as 88%, 79%, and 65% at 1, 3, and 5 years, respectively.

In 2006, Hernandez et al. reported on the contemporary performance of SVR based on data from the Society of Thoracic Surgeons’ (STS) database. (14) 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. (15) Improvement in a number of clinical variables was noted, including decreased left-ventricular dyssynchrony, reduced tricuspid regurgitation, and improved ejection fraction (27%–36%).

Searches of the MEDLINE database have found that the published studies continue to primarily report on case series. In many, SVR was performed in conjunction with additional cardiac procedures. For example, Tulner et al. reported on 6-month outcomes on 33 patients with class III/IV heart failure who underwent SVR and/or restrictive mitral annuloplasty. (16) 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. 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. (17) There were 3 operative deaths in each group. While there was symptomatic improvement in both groups, there was a trend toward reduced survival at 32 months in those with class IV versus class II/III disease (68% vs. 88%, respectively). A 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. (18) 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. While these and similar studies show that some clinical improvement occurs following this surgery, the non-randomized
nature of these studies limits the ability to draw conclusions. Controlled trials are needed to compare the outcomes of SVR to other alternatives.

Ongoing Clinical Trials
A search of online site ClinicalTrials.gov in July 2012 found the only active Phase III trial on surgical ventricular restoration is the Surgical Treatment of Ischemic Heart Failure (STICH) a randomized, multicenter, international, clinical trial to compare medical therapy with coronary artery bypass grafting (CABG) and/or SVR for patients with heart failure and coronary heart disease (NCT00023595). Although this trial is listed as ongoing, the main results of the CABG alone versus CABG plus surgical ventricular restoration have already been published and are reviewed in this reference policy.

Summary
Surgical ventricular restoration (SVR) is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in patients with akinetic segments of the heart, secondary to either dilated cardiomyopathy or post-infarction left ventricular aneurysm. A number of uncontrolled studies have suggested that surgical ventricular restoration can improve the hemodynamic functioning in selected patients with ischemic cardiomyopathy. However, the pivotal RCT, the STICH trial, did not report any improvements in clinical outcomes or quality-of-life measures for patients undergoing SVR in addition to standard CABG surgery. As a result of these data, the impact of SVR on net health outcome remains uncertain. Therefore, SVR is considered investigational.

Practice Guidelines and Position Statements
In 2010, a Task Force of the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery developed guidelines on myocardial revascularization. (19) These guidelines consider SVR combined with CABG to be a surgical option for patients with ischemic heart failure and left ventricular ejection fraction 35% or less (based on opinion and evidence that is not well-established). The guidelines also recommend SVR with CABG only be performed in centers with a high level of surgical expertise.

V. DEFINITIONS

Aneurysm refers to a localized abnormal dilatation of a blood vessel, usually an artery, due to a congenital defect or weakness in the wall of a vessel.

Cardiomyopathy is a disease of the myocardium (heart muscle) causing enlargement.
CONGESTIVE HEART FAILURE is an abnormal condition that reflects impaired cardiac pumping. Its causes include myocardial infarction, ischemic heart disease, and cardiomyopathy. Failure of the ventricles to eject blood efficiently results in volume overload, ventricular dilation, and elevated intracardiac pressure.

ELECTROSTIMULATION refers to the use of electric current to affect a tissue, such as a nerve, muscle, or bone.

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

LATISSIMUS DORSI is one of a pair of large triangular muscles on the thoracic and lumbar areas of the back.

MITRAL VALVE is the cardiac valve between the left atrium and left ventricle.

PERICARDIUM is the membranous fibroserous sac enclosing the heart and the bases of the great vessels.

SYNCHRONOUS means occurring simultaneously.

TACHYCARDIA is an abnormally rapid heart rate, greater than one hundred (100) beats per minute.

V. BENEFIT VARIATIONS
The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VI. DISCLAIMER
Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider.
and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

Partial Left Ventriculectomy

Surgical Ventricular Restoration

Taber’s Cyclopedic Medical Dictionary, 21st edition


### MEDICAL POLICY

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### VIII. CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Medically Necessary**

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IX. POLICY HISTORY

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|               |            | References reviewed and updated. Deleted FEP variation referencing MP 7.01.66 Partial Left Venticulectomy since this policy was archived. Added rationale section.