Anthem

Medical Policy

Subject: Partial Left Ventriculectomy
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Description/Scope

This document addresses partial left ventriculectomy, surgical ventricular remodeling/restoration procedures, and dynamic cardiomyoplasty.

Partial left ventriculectomy (PLV) is a surgical procedure aimed at improving the hemodynamic status of individuals with end-stage congestive heart failure (CHF) by directly reducing left ventricular size. This surgical approach to the treatment of CHF (also known as the Batista procedure or cardio-reduction) is primarily directed at individuals with an underlying dilated cardiomyopathy awaiting cardiac transplantation.

Surgical ventricular remodeling/restoration procedures refer to other techniques designed to restore or remodel the left ventricle to its normal shape or size and may also be referred to as ventricular remodeling, left ventricular reconstruction, endoventricular circular patch plasty, surgical anterior ventricular endocardial restoration (SAVER), or the Dor procedure.

This document also addresses dynamic cardiomyoplasty, a surgical procedure during which skeletal muscle tissue is wrapped around the diseased ventricle. The skeletal muscle is then electrically stimulated to beat in synchrony with the heart and is purported to thereby, improve ventricular functioning.

Position Statement

Investigational and Not Medically Necessary:

Partial left ventriculectomy is considered **investigational and not medically necessary** in all cases.

Other methods of remodeling or reshaping of the cardiac ventricles to reduce ventricle size with or without surgical removal, (for example, ventricular remodeling or reshaping procedures using ventricular wrapping [dynamic cardiomyoplasty], piercing, or clasping techniques) are considered **investigational and not medically necessary** in all cases.

Rationale

Partial Left Ventriculectomy (PLV)
The published medical literature consists primarily of single institution case series. This data is inadequate to permit conclusions regarding health benefits associated with partial left ventriculectomy (PLV). Specifically, the lack of controlled comparison of PLV to medical therapies or other types of “bridge to transplantation” (for example, ventricular assist devices) makes scientific assessment of the efficacy of this technique impossible, either in its role as a potential bridge to transplant or as an adjunct to medical therapy. The Society of Thoracic Surgeons (STS) issued a policy statement in 1997 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 (CHF) (STS, 1997). To date, the STS has not revised its position regarding PLV. Within updated STS information related to coding, the STS states the following:

> Since the mortality rate is high and there are no published scientific articles or clinical studies regarding partial ventriculectomy, this procedure cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Social Security Act. Therefore, partial ventriculectomy is not covered by Medicare (STS, 2005).

The American College of Cardiology/American Heart Association (ACC/AHA) Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult states, “Partial left ventriculectomy is not recommended in patients with nonischemic cardiomyopathy and refractory end-stage HF (Class III recommendation; Level of Evidence: C).” (Jessup, 2009)

An updated 2013 Guideline for the Management of Heart Failure from the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, which gave a Class IIb recommendation for surgical reverse remodeling based on preliminary results of the then-ongoing Surgical Treatment of Ischemic Heart Failure (STICH) trial (Jones, 2009), concluded as follows:

> Surgical reverse remodeling or LV aneurysmectomy may be considered in HFrEF (heart failure with reduced ejection fraction) for specific indications, including intractable HF and ventricular arrhythmias (Class IIb; Level of Evidence: B). (HFrEF is heart failure with reduced ejection fraction; Yancy, 2013.)

No additional specialty society recommendations or consensus statements were found that address ventriculectomy procedures.

The STICH trial was sponsored by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and Duke University. There were 2136 subjects recruited with CHF, left ventricular ejection fraction (LVEF) less than 35, and coronary artery disease (CAD) amenable to coronary artery bypass grafting (CABG) at 99 clinical sites. Trial participants with extensive anterior ischemia assigned to the surgical arm of the study were further randomized to CABG surgery alone versus CABG plus SVR. The study was extended to April 2016. The primary outcome was established as the rate of death from any cause. Major secondary outcomes included the rates of death from cardiovascular causes and of death from any cause or hospitalization for cardiovascular causes. Preliminary published information about this trial indicated that adding SVR to CABG reduced the left ventricular volume as compared with CABG alone. However, this anatomical change was not associated with a greater improvement in symptoms or exercise tolerance or with a reduction in the rate of death or hospitalization for cardiac causes (Buckberg, 2009; Jones, 2009; Mark, 2009; Zembala, 2010). Additional articles about the STICH trial continue to show no significant difference between the medical therapy alone group and medical therapy plus CABG with regard to the primary endpoint of death from any cause (Athanasuleas, 2015; Petrie, 2016; Piña, 2018; Prior, 2017; Velazquez, 2016).

Franco-Cereceda reported on the 1- and 3-year outcomes of 62 subjects with dilated cardiomyopathy (DCM) who underwent PLV. At the time of surgery, all subjects were either in New York Heart Association (NYHA) functional Class III or IV CHF. Survival was 80%

and 60% at 1 and 3 years after surgery, and freedom from failure was 49% and 26%, respectively. Although 80% of the trial subjects were alive at 1 year, this survival was achieved with the aggressive use of ventricular assist devices and transplantation as a salvage therapy. The authors concluded that PLV is not a predictable, reliable alternative to transplantation and that further investigations may be warranted that focus on the use of the procedure as a bridge to transplant, or its use in those not considered candidates for transplantation (Franco-Cereceda, 2001).

In 2003, the results of the Third International Registry Report were published, including data through 2002. This report noted that the incidence of PLV reached a peak by 1998 and was largely abandoned by 2000, except in Asia, where experienced institutions continue to perform the procedure in individuals in better condition with preserved myocardial contractility (Kawaguchi, 2003). According to the Fourth International Registry Report, published in 2005, the former 2002 Third International Registry was updated and expanded to include 568 cases voluntarily reported from 52 hospitals in 12 countries. The report concluded that avoidance of risk factors appears to have contributed to recent improvements in survival and restated that PLV has been largely abandoned except in Asia (Kawaguchi, 2005).

Surgical Ventricular Restoration (SVR)
The available evidence for SVR consists primarily of case series reports and retrospective reviews from single centers with the exception of publications from the multi-center RESTORE Group (Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the LV). The RESTORE Group is an international group of cardiologists and surgeons from 13 centers that has investigated SVR in over 1000 individuals with ischemic cardiomyopathy, following anterior myocardial infarction (MI) in the past 20 years (Athanasuleas, 2001a; Athanasuleas, 2001b; Asthanasuleas, 2004; DiDonato, 2004b, 2004c; DiDonato, 2001; Dor, 2001; Kawaguchi, 2003; Menicanti, 2001; Menicanti, 2002).

Athanasuleas from the RESTORE Group reported on early and 3-year outcomes in 662 individuals who underwent SVR following anterior MI during the period of January 1998 to July 2000. In addition to SVR, trial subjects also concomitantly underwent CABG (92%), mitral repair (22%), and mitral replacement (3%). The authors reported overall mortality during hospitalization was 7.7%; postoperative LVEF increased from 29.7% ± 11.3% to 40.0% ± 12.3% ($p<0.05$). The survival rate and freedom from hospitalization for CHF at 3 years was 89.4% ± 1.3% and 88.7% respectively. In a separate publication on 439 subjects from the RESTORE Group, Athanasuleas reported outcomes improved in those with younger age, higher LVEF and lack of need for mitral valve replacement (Athanasuleas, 2001a; 2001b).

Mickleborough reported on 285 trial subjects who underwent SVR by a single surgeon for Class III or IV CHF, angina or ventricular tachyarrhythmia during the period of 1983 to 2002. In addition to SVR, trial subjects 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 subjects. The authors reported hospital mortality of 2.8%; postoperative LVEF increased 10% ± 9% from 24% ± 11% ($p<0.000$) and symptom class in 140 subjects improved 1.3 ± 1.1 functional class per subject. Trial participants were followed 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 case selection (Mickleborough, 2004).

Bolooki reported on 157 individuals who underwent SVR by a single surgeon for Class III or IV CHF, angina, ventricular tachyarrhythmia or MI using three operative methods during the period of 1979 to 2000. 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 LVEF was 28% ± 0.9%. Trial participants were followed for up to 22 years, and overall actuarial survival was reported as 53%, 30%, and 18% at 5, 10 and 15 years respectively. The authors found factors improving long-term survival included SVR with intraventricular patch repair and having an LVEF of 26% or greater preoperatively (Bolooki, 2003).

Another small study reported on 101 individuals who underwent SVR using the Dor procedure at a single center for Class III or IV CHF, angina and ventricular tachyarrhythmia during the period of 1994 to 2004. In addition to SVR, trial subjects also concomitantly underwent CABG (98%), arrhythmia ablation (52%) and a mitral valve procedure (29%). The authors reported early mortality (within 30 days of operation) was 7.9%; and LVEF increased from 27% ± 9.9% to 33% ± 9.3% postoperatively. Trial participants 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 (Sartipy, 2005).

Summary
While the SVR procedure has been performed for many years, the available data are inadequate to permit conclusions regarding its health benefits. Additionally, selection criteria and optimal surgical techniques are still undetermined.

Background/Overview

Partial Left Ventriculectomy (PLV)
PLV is a surgical procedure aimed at improving the hemodynamic status of individuals with end stage CHF by directly reducing the left ventricular size. This surgical approach to the treatment of CHF, (also known as the Batista procedure, cardio-reduction, and left ventricular remodeling surgery) is primarily directed at those with an underlying dilated cardiomyopathy awaiting cardiac transplantation. PLV has been investigated as either a “bridge” to transplantation or as an alternative to heart transplantation.

Surgical Ventricular Restoration (SVR)
SVR is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in individuals with akinetic segments of the heart, secondary to either dilated cardiomyopathy or post MI left ventricular aneurysm. The SVR procedure is usually performed after CABG and may precede or be followed by mitral valve repair or replacement. A key difference between PLV and SVR is that in SVR the ventricle is reconstructed using patches of autologous or artificial material that are placed to close the defect while maintaining the desired ventricular volume and contour.

Additional techniques of ventricular reshaping include, but are not limited, to:

- Wrapping a mesh sling (Acorn CorCap™ Wrap) around the right and left ventricle to decrease the size of the ventricles;
- Applying pads to each side of the enlarged ventricle and attaching them via cords/cables that are then tightened resulting in a decrease in the size of the ventricle (Myosplint®).

The Acorn CorCap™ Cardiac Support Device (Acorn Cardiovascular, St. Paul, MN) has not received FDA clearance, because sufficient evidence regarding its safety and efficacy has not yet been established in the published literature. Another device, the Myosplint® formerly manufactured by Myocor Inc. (Maple Grove, MN) is no longer being produced or investigated, since Myocor went out of business in 2008.

Definitions

Dynamic Cardiomyoplasty: This surgical procedure involves a latissimus dorsi muscle flap which is transposed into the chest and wrapped around the ventricles of the failing heart. This skeletal muscle flap is then electrically stimulated to contract in synchrony with ventricular pumping of the heart. Researchers have proposed that this muscle wrap may provide an external constraint that reduces progressive ventricular dilatation and remodeling, thereby decreasing wall tension in the ventricle and improving ventricular function.

Partial Left Ventriculectomy (PLV [also known as the Batista procedure]):This surgical procedure reduces the size of the left ventricle by resecting (removing) a portion of the left ventricle, which is the pumping chamber of the heart that delivers blood to the body. This is typically done in an attempt to relieve some of the symptoms of severe CHF and is usually done in conjunction with additional cardiac surgical procedures, such as mitral valve annuloplasty or replacement.

Surgical Ventricular Restoration (SVR [also known as the Dor procedure]):This surgical procedure involves an incision into the left ventricle to exclude, but not remove, the damaged area. A remodeling device is then temporarily inserted into the ventricle around which the heart wall is then stretched, thereby reducing the diameter and restoring the shape of the left ventricle. Thereafter, the device is removed, and the opening is closed with sutures and/or a patch.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services are Investigational and Not Medically Necessary:

CPT	
33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedures)
33999	Unlisted procedure, cardiac surgery [when specified as Batista procedure (partial left ventriculectomy) or dynamic cardiomyoplasty]

ICD-10 Diagnosis	
	All diagnoses

When services are also Investigational and Not Medically Necessary:

ICD-10 Procedure	
02BL0ZZ	Excision of left ventricle, open approach
02HL0DZ	Insertion of intraluminal device into left ventricle, open approach
02UA07Z	Supplement heart with autologous tissue substitute, open approach
02UK07Z	Supplement right ventricle with autologous tissue substitute, open approach
02UL07Z	Supplement left ventricle with autologous tissue substitute, open approach

ICD-10 Diagnosis	
I42.0	Dilated cardiomyopathy
I50.1-I50.9	Heart failure

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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	05/12/2022	MPTAC review. References were updated.
Reviewed	05/13/2021	MPTAC review. Information in the Rationale section was reorganized and References were updated.
Reviewed	05/14/2020	MPTAC review. The Background and References sections were updated.
Revised	06/06/2019	MPTAC review. The position statement was revised to remove the acronym for partial left ventriculectomy (PLV). References were updated.
Reviewed	07/26/2018	MPTAC review. The document header wording was updated from “Current Effective Date” to “Publish Date.” The Rationale and References sections were updated.
Reviewed	08/03/2017	MPTAC review. The References were updated.
Reviewed	08/04/2016	MPTAC review. The References were updated. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. The Rationale and References were updated.
Reviewed	08/14/2014	MPTAC review. The Rationale and References were updated.
Reviewed	08/08/2013	MPTAC review. The Rationale and References were updated.
Reviewed	08/09/2012	MPTAC review. The Rationale and References were updated.
Reviewed	08/18/2011	MPTAC review. The Rationale, Coding and References were updated.
Reviewed	08/19/2010	MPTAC review. The Rationale and References were updated.
Reviewed	08/27/2009	MPTAC review. The Rationale and References were updated.
Reviewed	08/28/2008	MPTAC review. References were updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	08/23/2007	MPTAC review. Rationale, Background, and References were updated.
Reviewed	09/14/2006	MPTAC review. References and definitions were updated.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/27/2004	SURG.00005	Partial Left Ventriculectomy, Dynamic Cardiomyoplasty
WellPoint Health Networks, Inc.			No document

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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 eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.