



# Louisiana

## **Surgical Ventricular Restoration**

**Policy #** 00184

**Original Effective Date:** 01/26/2006

**Current Effective Date:** 06/10/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

## **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data the Company considers surgical ventricular restoration (SVR) for the treatment of ischemic dilated cardiomyopathy to be **investigational**.\*

## **Policy Guidelines**

Surgical ventricular restoration involves increased physician work compared with standard ventriculectomy. For example, the procedure includes evaluation of the ventricular septum and reshaping of the geometry of the heart. Surgical ventricular restoration is described as a global treatment of left ventricular failure, while conventional left ventricular aneurysmectomy represents a local treatment of a transmural infarct.

## **Background/Overview**

### **Surgical Ventricular Restoration**

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

Surgical ventricular restoration is usually performed after coronary artery bypass grafting and may precede or be followed by mitral valve repair or replacement and other procedures such as endocardectomy and cryoablation for treatment of ventricular tachycardia. A key difference between SVR and ventriculectomy (ie, 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

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together, and restore a more normal ventricular contour. If the defect is large (ie, 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 (ie, the Batista procedure), which does not attempt specifically to resect akinetic segments and restore ventricular contour.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

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 apolypropylene, polyethylene terephthalate, or polytetrafluoroethylene patch or pledget placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures. Biological tissue may also be a component of the patches. In 2004, the CorRestore<sup>TM‡</sup> 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<sup>®‡</sup> ventricular restoration system. This exemption allows Ancora Heart to proceed with an initial efficacy and safety study in individuals with heart failure and reduced ejection fraction.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Surgical ventricular restoration is 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 ischemic dilated cardiomyopathy.

### **Summary of Evidence**

For individuals who have ischemic dilated cardiomyopathy who receive surgical ventricular restoration (SVR) as an adjunct to coronary artery bypass grafting (CABG), the evidence includes a large randomized controlled trial (RCT) (another RCT reported results, but most trial enrollees overlapped with those in the larger trial) and uncontrolled studies. Relevant outcomes are overall survival, symptoms, quality of life, hospitalizations, resource utilization, and treatment-related morbidity. The RCT, the Surgical Treatment of Ischemic Heart Failure trial, did not report significant improvements in quality of life outcomes for individuals undergoing SVR as an adjunct to standard CABG surgery. Several uncontrolled studies have suggested that SVR can improve hemodynamic functioning in selected individuals with ischemic cardiomyopathy; however, these studies are considered lower quality evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Supplemental Information**

### **Practice Guidelines and Position Statement**

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

### **American Association for Thoracic Surgery**

The American Association for Thoracic Surgery published an expert consensus document on coronary artery bypass grafting (CABG) in individuals with ischemic cardiomyopathy and heart failure in 2021. The document notes that tenets of surgical ventricular restoration (SVR) at the time of CABG that may "confer the most benefit to individuals include resection of scarred myocardium, reducing ventricular size, and restoring an anatomically elliptical shape"; however, the document notes that "it remains uncertain which individuals should receive [SVR] as part of the CABG operation and what the impact is on long-term survival and functional outcome." The American

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# Louisiana

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Association for Thoracic Surgery does state that "concomitant SVR should be considered for individuals with a true left ventricular aneurysm" (class of recommendation: IIa; level of evidence: B-R).

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

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

### Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04489355	Assessment of Risks and Outcomes of Surgical Intervention in Individuals with Ischemic Cardiomyopathy in the Early and Long-Term Postoperative Period, Selection of Optimal Surgical Treatment	260	May 2024
NCT03183895 <sup>a</sup>	Safety and Performance Evaluation of the AccuCinch <sup>®‡</sup> 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 <sup>a</sup>	Randomized Clinical Evaluation of the AccuCinch <sup>®‡</sup> Ventricular Restoration System in	400	Dec 2030

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	Individuals Who Present with Symptomatic Heart Failure With Reduced Ejection Fraction (HFrEF): The CORCINCH-HF Study		
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<sup>a</sup>Denotes industry-sponsored or cosponsored trial

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# Louisiana

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# Louisiana

## Surgical Ventricular Restoration

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## **Policy History**

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Current Effective Date: 06/10/2024

- |            |  |
|------------|--|
| 01/04/2006 | Medical Director review  |
| 01/17/2006 | Medical Policy Committee review  |
| 01/26/2006 | Quality Care Advisory Council approval   |
| 07/07/2006 | Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. |
| 01/10/2007 | Medical Director review  |
| 01/17/2007 | Medical Policy Committee approval  |
| 01/07/2009 | Medical Director review  |
| 01/14/2009 | Medical Policy Committee approval. No change to coverage.  |
| 01/07/2010 | Medical Policy Committee approval  |
| 01/20/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  |
| 01/06/2011 | Medical Policy Committee review  |
| 01/19/2011 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  |
| 03/01/2012 | Medical Policy Committee review  |
| 03/21/2012 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  |
| 03/07/2013 | Medical Policy Committee review  |
| 03/20/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  |
| 03/06/2014 | Medical Policy Committee review  |
| 03/19/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  |

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03/05/2015 Medical Policy Committee review  
03/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.  
03/03/2016 Medical Policy Committee review  
03/16/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes  
05/04/2017 Medical Policy Committee review  
05/17/2017 Medical Policy Implementation Committee approval. Deleted “or postinfarction left ventricular aneurysm” from the policy statement.  
05/03/2018 Medical Policy Committee review  
05/16/2018 Medical Policy Implementation Committee approval. No change to coverage.  
05/02/2019 Medical Policy Committee review  
05/15/2019 Medical Policy Implementation Committee approval. No change to coverage.  
05/07/2020 Medical Policy Committee review  
05/13/2020 Medical Policy Implementation Committee approval. No change to coverage.  
05/06/2021 Medical Policy Committee review  
05/12/2021 Medical Policy Implementation Committee approval. No change to coverage.  
05/05/2022 Medical Policy Committee review  
05/11/2022 Medical Policy Implementation Committee approval. No change to coverage.  
05/04/2023 Medical Policy Committee review  
05/10/2023 Medical Policy Implementation Committee approval. No change to coverage.  
05/02/2024 Medical Policy Committee review  
05/08/2024 Medical Policy Implementation Committee approval. No change to coverage.  
Next Scheduled Review Date: 05/2025

## **Coding**

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# Louisiana

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Policy # 00184

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Current Effective Date: 06/10/2024

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33548
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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# Louisiana

## Surgical Ventricular Restoration

Policy # 00184

Original Effective Date: 01/26/2006

Current Effective Date: 06/10/2024

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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# Louisiana

## Surgical Ventricular Restoration

Policy # 00184

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**NOTICE:** 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.

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