# Surgical Ventricular Restoration

**Policy #** 00184
Original Effective Date: 01/26/2006
Current Effective Date: 06/08/2020

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

SVR 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 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 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 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.

# Rationale/Source

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

For individuals who have ischemic dilated cardiomyopathy who receive SVR as an adjunct to coronary artery bypass grafting, the evidence includes a large randomized controlled trial (another randomized controlled trial reported results, but most trial enrollees overlapped with those in the larger trial) and uncontrolled studies. The relevant outcomes are overall survival, symptoms, quality of life, hospitalizations, resource utilization, and treatment-related morbidity. The randomized controlled trial, the Surgical Treatment of Ischemic Heart Failure trial, did not report significant improvements in quality of life outcomes for patients undergoing SVR as an adjunct to standard coronary artery bypass grafting 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 the effects of the technology on health outcomes.

# Supplemental Information

**Practice Guidelines and Position Statement**

**European Society of Cardiology and European Association for Cardio-Thoracic Surgery**
The European Society of Cardiology and the European Association for Cardio-Thoracic Surgery (2018) developed joint guidelines on myocardial revascularization. The guidelines indicate that surgical ventricular restoration during coronary artery bypass grafting may be considered in selected patients treated in centers with the requisite expertise.

**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**
A search of ClinicalTrials.gov in December 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

# References

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# Policy History

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01/04/2006 Medical Director review
01/17/2006 Medical Policy Committee review

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|---|---|
| 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. |
| 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. |

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Next Scheduled Review Date: 05/2021

# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

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 diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**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.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.