Medical Coverage Policy | Surgical Ventricular Restoration

EFFECTIVE DATE: 05|01|2017
POLICY LAST UPDATED: 03|03|2021

OVERVIEW
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.

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see Related Policies section.

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
Surgical ventricular restoration is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For Medicare Advantage Plans, see related policy section for the Medicare Advantage Plans National and Local Coverage Determinations policy.

MEDICAL CRITERIA
Not applicable

BACKGROUND
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 (ie, the Batista procedure), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

The U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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.

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.

For individuals who have ischemic dilated cardiomyopathy who receive SVR as an adjunct to CABG, the evidence includes a large 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 patients undergoing SVR as an adjunct to standard CABG 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 that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

CODING

Commercial Products

The following CPT code is not medically necessary:

33548 Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg,ventricular remodeling, SVR, SAVER, Dor procedures)

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations

PUBLISHED

Provider Update, May 2021
Provider Update, May 2020
Provider Update, June 2019
Provider Update, June 2018
Provider Update, May 2017

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