

(701103)

Medical Benefit		Effective Date: 04/01/18	Next Review Date: 01/21
Preauthorization	No	Review Dates: 03/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With ischemic dilated cardiomyopathy 	Interventions of interest are: <ul style="list-style-type: none"> • Surgical ventricular restoration as an adjunct to standard coronary artery bypass grafting 	Comparators of interest are: <ul style="list-style-type: none"> • Coronary artery bypass grafting 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Symptoms • Quality of life • Hospitalizations • Resource utilization • Treatment-related morbidity

DESCRIPTION

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.

SUMMARY OF EVIDENCE

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. 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.

POLICY

Surgical ventricular restoration is considered **investigational** for the treatment of ischemic dilated cardiomyopathy.

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

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 (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 more than 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), which does not attempt specifically to resect akinetic segments and restore ventricular contour.

REGULATORY STATUS

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. Food and Drug Administration product code: DXZ.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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