BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Surgical Ventricular Restoration

Policy #: 257
Category: Surgery

Latest Review Date: February 2021
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **surgical ventricular restoration** as a **non-covered** benefit and as **investigational** for the treatment of ischemic dilated cardiomyopathy.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination

DESCRIPTION OF PROCEDURE OR SERVICE:

Surgical ventricular restoration (SVR) is a procedure 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.

The SVR procedure is usually performed after coronary artery bypass grafting (CABG) 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 surgical ventricular restoration 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 >3cm), 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 to specifically resect akinetic segments and restore ventricular contour.

SVR may also be referred to as surgical anterior ventricular endocardial restoration (SAVER), left ventricular reconstructive surgery, endoventricular circular plasty, or the Dor procedure after Vincent Dor, M.D. Dr. Dor pioneered expansion of techniques for ventricular reconstruction and is credited with treating congestive heart failure patients with SVR in conjunction with CABG.

KEY POINTS:

The most recent literature search was performed through January 3, 2021.

Summary

For individuals who have ischemic dilated cardiomyopathy who receive SVR as an adjunct to CABG, the evidence includes a single large randomized controlled trial (RCT) (another RCT reported results, but most of the patients overlapped with those in the larger trial) and uncontrolled studies. Relevant outcomes are survival, quality of life (QOL), hospitalizations,

resource utilization, and treatment related morbidity. The RCT, the Surgical Treatment of Ischemic Heart Failure (STICH) trial, did not report significant improvements in QOL outcomes for patients undergoing SVR in addition to standard CABG surgery. Several uncontrolled studies have suggested that SVR can improve the 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.

Practice Guidelines and Position Statements

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; update in progress) 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

Surgical ventricular restoration is not a preventive service.

KEY WORDS:

DOR procedure, surgical anterior endocardial restoration (SAVER), surgical ventricular restoration (SVR), ventricular restoration or remodeling, CorRestore™

APPROVED BY GOVERNING BODIES:

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 Medtroinc) is a device cleared by the U.S. Food and Drug Administration through the 510(k) process that is specifically labeled 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. Product code: DXZ.

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.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, DOR procedure)

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POLICY HISTORY:

Adopted for Blue Advantage, October 2005
Available for comment October 28-December 12, 2005
Medical Policy Group, October 2007
Medical Policy Group, October 2009
Medical Policy Group, August 2011
Medical Policy Group, August 2012
Medical Policy Group, August 2013
Medical Policy Group, August 2014
Medical Policy Group, August 2015
Medical Policy Group, February 2016
Medical Policy Group, March 2017
Medical Policy Group, February 2018
Medical Policy Group, February 2020
Medical Policy Group, February 2021

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.