AETNA BETTER HEALTH®

Clinical Policy Bulletin:
Selected Aortic Valve Procedures:
Ross Pulmonary Autograft and Aortic Valve-Sparing Re-implantation

Number: 0407

Policy

I. Aetna considers the Ross pulmonary autograft procedure medically necessary for members undergoing aortic valve replacement secondary to either congenital anomalies or aortic valve disease, such as:

   A. Aortic incompetence (including endocarditis, rheumatism of the heart); or
   B. Aortic stenosis; or
   C. Complex left ventricular outflow tract obstruction; or
   D. Congenital lesions.

Contraindications to this procedure are presented as an Appendix to the Background section.

Aetna considers the Ross pulmonary autograft experimental and investigational for all other indications (e.g., middle-aged or older adults when suitable alternatives to autograft replacement of the aortic valve are available with comparable results and without the need for replacement of the right ventricular outflow tract, and individuals with bicuspid valves and aortic regurgitation or aortic dilation if other alternatives are available) because its effectiveness for indications other than the ones listed above has not been established.

II. Aetna considers the minimally invasive approach to the aortic valve a medically necessary acceptable alternative to the conventional approach to aortic valve replacement.

III. Aetna considers aortic valve-sparing re-implantation medically necessary for the treatment of secondary aortic regurgitation due to aortic root
dilatation as occurs in Marfan syndrome as well as for the treatment of type A acute aortic dissections (i.e., dissection of the ascending and descending aorta).

Aetna considers aortic valve sparing re-implantation experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

IV. Aetna considers aortic valve-sparing procedures medically necessary for the treatment of aortic root ectasia, and dissection and aneurysms of the ascending aorta.

Background

Patients undergoing aortic valve replacement may consider 3 options: (i) a prosthetic valve, (ii) a homograft valve, or (iii) a pulmonary autograft (i.e., the Ross procedure). Ross pulmonary autograft refers to essentially a double valve replacement in which the native pulmonic valve is substituted for the diseased aortic valve, while a homograft prosthetic valve replaces the pulmonic valve. This procedure was first devised in 1967 and sought to provide a permanent aortic valve substitution, which would not degenerate like a homograft valve and would not require chronic anti-coagulation therapy like a prosthetic valve. The risk:benefit ratio involves a balance between a more complicated surgical procedure (essentially a double valve replacement) and a potentially more durable and physiologic aortic valve replacement. Furthermore, it is thought that the autografted pulmonary valve will grow with the young patient, thus obviating the need for re-operation. Studies have also shown that the Ross procedure resulted in significant improvement in left ventricular wall thickness and outflow tract velocity not observed in allograft aortic valve replacements in children. For these reasons, the Ross procedure is considered most appropriate for young adults. Candidates for this procedure should be adequately counseled on the various valve replacement alternatives.

In a systematic review and meta-analysis, Takkenberg et al (2009) stated that the Ross procedure provides satisfactory results for both children and young adults (less than or equal to 50 years of age). Furthermore, David (2009) noted that young adults with aortic stenosis and normal-size aortic root are the best candidates for the Ross procedure.

Aortic valve-sparing re-implantation is a valve-sparing technique employed for patients with aortic regurgitation secondary to aortic root dilatation in which valvular insufficiency is due to outward displacement of the valve commissures. This technique, which is different from aortic valve repair, has the advantages of lack of requirement for anti-coagulation and avoidance of other problems and complications associated with mechanical prosthetic valves. Although primarily used for secondary aortic regurgitation due to root dilatation as occurs in Marfan syndrome, guidelines from the European Society of Cardiology (Erbel et al, 2001) stated that aortic valve-sparing re-implantation may also be indicated for patients with type A acute aortic dissections (i.e., dissection of the ascending and descending aorta).
The Society of Thoracic Surgeons’ “Aortic valve and ascending aorta guidelines for management and quality measures” (Svensson et al, 2013) stated that

The Ross procedure is not recommended for middle-aged or older adults when suitable alternatives to autograft replacement of the aortic valve are available with comparable results and without the need for replacement of the right ventricular outflow tract (RVOT), as the latter adds the additional risk of pulmonary valve dysfunction and subsequent replacement. (Level of evidence C)

The Ross procedure is not recommended for patients with bicuspid valves and aortic regurgitation or aortic dilation if other alternatives are available. (Level of evidence C)

Guidelines from the European Society of Cardiology (Erbel, et al., 2014) state that in most cases of aortic insufficiency associated with acute Type A dissection, the aortic valve is essentially normal and can be preserved by applying an aortic valve-sparing repair of the aortic root. In cases of aneurysms of the ascending aorta, where total replacement is indicated, the choice between a valve-sparing intervention and a composite graft with a valve prosthesis depends on the analysis of aortic valve function and anatomy, the size and site of TAA, life expectancy, desired anticoagulation status, and the experience of the surgical team.

Similarly, guidelines from the American College of Cardiology (Hiratzka, et al., 2010) state that extensive dissection of the aortic root should be treated with aortic root replacement with a composite graft or with a valve sparing root replacement.

Stephens et al (2014) examined if recurrent or residual mild aortic regurgitation, which occurs after valve-sparing aortic root replacement, progresses over time. Between 2003 and 2008, a total of 154 patients underwent Tirone David-V valve-sparing aortic root replacement; 96 patients (62 %) had both 1-year (median of 12 ± 4 months) and mid-term (62 ± 22 months) transthoracic echocardiograms available for analysis. Age of patients averaged 38 ± 13 years, 71 % were male, 31 % had a bicuspid aortic valve, 41 % had Marfan syndrome, and 51 % underwent aortic valve repair, predominantly cusp free margin shortening. A total of 41 patients (43 %) had mild aortic regurgitation on 1-year echocardiogram. In 85 % of patients (n = 35), mild aortic regurgitation remained stable on the most recent echocardiogram (median of 57 ± 20 months); progression to moderate aortic regurgitation occurred in 5 patients (12 %) at a median of 28 ± 18 months and remained stable thereafter; severe aortic regurgitation developed in 1 patient, eventually requiring re-operation. Five patients (5 %) had moderate aortic regurgitation at 1 year, which did not progress subsequently. Two patients (2 %) had more than moderate aortic regurgitation at 1 year, and both ultimately required re-operation. The authors concluded that although mild aortic regurgitation occurs frequently after valve-sparing aortic root replacement, it is unlikely to progress over the next 5 years and should not be interpreted as failure of the valve-preservation concept. Further, these investigators suggested that mild aortic regurgitation should not be considered non-structural valve dysfunction, as the 2008 valve reporting guidelines would indicate. The authors noted that 10- to 15-year follow-up is needed to learn the long-term clinical consequences of mild aortic regurgitation early after valve-sparing aortic root replacement.
In a retrospective study, Gamba and colleagues (2015) evaluated their experience of using a simplified aortic valve sleeve procedure to treat aortic root ectasia and aneurysms with or without aortic regurgitation. In experienced hands, 2 aortic valve-sparing procedures, namely, Yacoub and David, have yielded excellent long-term results in the treatment of aortic root aneurysms, with or without aortic regurgitation. However, these techniques are demanding and not widely used. Recently, a new and simplified valve-sparing technique, named "sleeve procedure", has been proposed, and has yielded encouraging early results. A total of 90 consecutive patients with aortic root aneurysms underwent sleeve procedures from October 2006 to October 2012. Follow-up data (clinical 100 % complete and echocardiographic 93 % complete) were acquired from the authors' out-patient clinic or from the referring cardiologist. The mean age of the patients was 61.5 ± 12.5 years, 79 % were male, 16 (18 %) had a bicuspid valve, 3 had Marfan syndrome, and 2 had aortic dissection. Over a mean clinical follow-up of 34 ± 19 months, 2 patients died from non-cardiac causes and 1 was re-operated on for the recurrence of aortic regurgitation. On follow-up echocardiography after a mean of 18 ± 9 months, aortic regurgitation was absent/negligible, mild or moderate in 62 %, 37 %, and 1 % of patients, respectively, and the diameters of the annulus, Valsalva sinuses, and sino-tubular junction were 27.3 ± 2.2, 37.0 ± 3.4, and 30.6 ± 3.1 mm, respectively. The authors concluded that these encouraging early and medium term results suggested that the sleeve procedure is a safe and effective aortic valve-sparing technique for the treatment of aortic root ectasia and aneurysm. However, they stated that longer follow-up is needed in order to draw definitive conclusions.

Appendix

The pulmonary autograft procedure is contraindicated in individuals with the following conditions:

- Extremes of age; or
- Marfan's syndrome; or
- Multiple pathology in which a second valve replacement device is needed; or
- Multi-vessel coronary artery disease; or
- Severely depressed left ventricular function.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

33413  Replacement, aortic valve; by translocation of autologous pulmonary valve with allograft replacement of pulmonary valve (Ross procedure)

33400  Valvuloplasty, aortic valve
33403
ICD-9 codes covered if selection criteria are met:

395.0  Rheumatic aortic stenosis
395.1  Rheumatic aortic insufficiency
424.1  Aortic valve disorders [not covered for individuals with bicuspid valves and aortic regurgitation or aortic dilation if other alternatives are available]
441.00 - Dissection of aorta
441.03
447.70  Aortic ectasia [aortic dilation] [not covered for individuals with bicuspid valves and aortic regurgitation or aortic dilation if other alternatives are available]
747.20 - Other anomalies of aorta
747.29
746.3  Congenital stenosis of aortic valve
746.4  Congenital insufficiency of aortic valve

Other ICD-9 codes related to the CPB:

396.0 - 396.9  Disease of mitral and aortic valve
414.00 - Coronary atherosclerosis
414.07
745.0  Common truncus
746.89 - Other and unspecified anomaly of heart
746.9
747.10 - Coarctation of aorta
747.11
759.82  Marfan syndrome
V42.2  Heart valve replaced by transplant
V43.3  Heart valve replaced by other means

The above policy is based on the following references:


