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

Number: 0407

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

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-implanatation 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. Bavaria and colleagues (2015) noted that valve-sparing root reimplantation (VSRR) in tricuspid aortic valve (TAV) patients is well-established, but in bicuspid aortic valve (BAV) patients, it has been less widely adopted. These investigators examined if valve type affects mid-term outcomes with VSRR. They performed a retrospective review of 186 patients who underwent an aortic valve-sparing root reimplantation operation between 2004 and 2013. Of these, 129 patients underwent elective VSRR with the David V technique. Outcomes were compared in this cohort by valve type: TAV (n = 89) versus BAV (n = 40). Demographics were similar in the 2 groups -- BAV patients had a higher degree of aortic insufficiency (AI) at presentation (p < 0.05), and an enlarged pre-operative annulus (30 ± 4 versus 28 ± 6 mm, p = 0.06). All BAV patients required primary leaflet repair (6 % in the TAV group; p < 0.01). Post-operative mortality (0), stroke (0 % versus 1 %), and pacemaker requirement (0 % versus 5 %) were similar. Post-operative freedom from AI grade greater than or equal to 2+ was 100 % in the entire cohort, and trans-valvular gradients were similar. At follow-up, a 1-year echocardiogram (ECG) showed higher peak and mean trans-valvular gradients in the BAV group (p < 0.01). One TAV group patient died from an unknown cause. The 5-year actuarial freedom from aortic
valve reoperation was 100 % versus 97 % ± 3 % (p = 0.6); 3 patients in the entire cohort have had AI grade greater than 2+ on follow-up (n = 1 in the BAV group; n = 2 in the TAV group). The authors concluded that even though BAV patients presented with higher AI grade and required concomitant primary valve repair, the VSRR David V technique offered excellent mid-term outcomes with both the BAV and TAV valve types.

Malvindi and associates (2015) stated that aortic valve-sparing operation has been progressively widely performed for the treatment of aortic root aneurysm. Nowadays, this procedure has been proposed even in presence of a BAV, severe aortic regurgitation or in primary aortic dissection repair. These investigators presented their 10-year experience focusing on mid-term ECG follow-up. Between June 2002 and February 2012, a total of 139 patients (mean age of 61 ± 12 years) underwent aortic valve-sparing operation with valve reimplantation; 27 patients (19 %) had BAV; in 18 cases (13 %) cusp motion or anatomical abnormalities concurred in determining aortic regurgitation and needed an adjunct cusp repair. A Gelweave Valsalva graft was implanted in all the patients. The mortality pre-discharge was 0.7 % (1 patient). The cumulative 1-year, 5-years and 8-years survival rates were 99 %, 93 % and 87 %, respectively. Post-operative aortic regurgitation more than mild degree (greater than 2+4+) was the only significant risk factors for redo aortic valve surgery freedom from reoperation due to aortic valve regurgitation was 96 % at 1 year, 90 % at 5 years and 86 % at 8 years. When comparing freedom from reoperation in patients with BAV versus TAV, no differences were found (p = 0.31) and the rate of aortic valve reoperation was significantly higher (p < 0.001) in patients who received leaflet's repair. The authors concluded that the durability of valve reimplantation was found to be excellent in patients with TAV and normal or nearly normal cusps. Cusp prolapse and complication after cusp repair turned out to be the main causes for early failure.

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-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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)
- 33390 - 33391 Valvuloplasty, aortic valve, open, with cardiopulmonary bypass

ICD-10 codes covered if selection criteria are met:

- I06.0 Rheumatic aortic stenosis
- I06.1 Rheumatic aortic insufficiency
- I35.0 - I35.9 Nonrheumatic aortic valve disorders [not covered for individuals with bicuspid valves and aortic regurgitation or aortic dilation if other alternatives are available]
The above policy is based on the following references:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0407 Selected Aortic Valve Procedures: Ross Pulmonary Autograft and Aortic Valve-Sparing Re-implantation

There are no amendments for Medicaid.

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