Heart valve transplant

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Policy contains: aortic allograft valve, bioprosthetic heart valve, Ross procedure, sutureless aortic valve replacement, transcatheter aortic valve replacement, valvular heart disease.

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Coverage policy

Heart valve transplants are clinically proven and, therefore, medically necessary when any of the following indications are present (Nishimura, 2014; Nishimura, 2017):

Note: Indications are for valve replacement, not repair or other valve procedures.

Aortic stenosis.

- Symptomatic members with severe high-gradient aortic stenosis.
- Asymptomatic members with severe aortic stenosis and left ventricular ejection fraction <50%.
- Severe aortic stenosis when undergoing other cardiac surgery.
- Asymptomatic members with very severe aortic stenosis and low surgical risk.
- Asymptomatic members with severe aortic stenosis and decreased exercise tolerance or an exercise fall in blood pressure.
- Symptomatic members with low-flow/low-gradient severe aortic stenosis with reduced left ventricular ejection fraction with a low-dose dobutamine stress study that shows an aortic velocity ≥4.0 m/s (or mean pressure gradient ≥40 mm Hg) with a valve area <1 cm^2 at any dobutamine dose.

- Symptomatic members who have low-flow/low-gradient severe aortic stenosis who are normotensive and have a left ventricular ejection fraction ≥50% if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms.
- Members with moderate aortic stenosis who are undergoing other cardiac surgery.
- Asymptomatic members with severe aortic stenosis and rapid disease progression and low surgical risk.

Aortic regurgitation.

- Symptomatic members with severe aortic regurgitation regardless of left ventricular systolic function.
- Asymptomatic members with chronic severe aortic regurgitation and left ventricular systolic dysfunction <50%.
- Members with severe aortic regurgitation while undergoing cardiac surgery for other indications.
- Asymptomatic members with severe aortic regurgitation with normal left ventricular systolic function (left ventricular ejection fraction ≥50%) but with severe left ventricular dilation (left ventricular end-systolic dimension ≥50 mm).
- Members with moderate aortic regurgitation who are undergoing other cardiac surgery.
- Asymptomatic members with severe aortic regurgitation and normal left ventricular systolic function (left ventricular ejection fraction ≥50%) but with progressive severe left ventricular dilation (left ventricular end-diastolic dimension ≥65 mm) if surgical risk is low.

Bicuspid aortic valve and aortopathy.

- To replace the ascending aorta in members with a bicuspid aortic valve if the diameter of the aortic sinuses or ascending aorta is greater than 5.5 cm.
- To replace the ascending aorta in members with bicuspid aortic valves if the diameter of the aortic sinuses or ascending aorta is greater than 5.0 cm and a risk factor for dissection is present (family history of aortic dissection or if the rate of increase in diameter is ≥0.5 cm per year).
- Replacement of the ascending aorta in members with a bicuspid aortic valve who are undergoing aortic valve surgery because of severe aortic stenosis or aortic regurgitation (3.4 Timing of Intervention, 4.4 Timing of Intervention) if the diameter of the ascending aorta is greater than 4.5 cm.

Mitral stenosis.

- Mitral valve surgery (including valve replacement) in severely symptomatic members (New York Heart Association class III to IV) with severe mitral stenosis (mitral valve area <1.5 cm^2) who are not high risk for surgery and who are not candidates for or who have failed previous percutaneous mitral balloon commissurotomy.

Mitral regurgitation.

- Concomitant mitral valve repair or replacement in members with chronic severe primary mitral regurgitation undergoing cardiac surgery for other indications.
- Mitral valve repair or replacement for severely symptomatic members (New York Heart Association class III to IV) with chronic severe secondary mitral regurgitation (stage D) who have persistent symptoms despite optimal guideline-directed medical therapy for heart failure.

Tricuspid regurgitation.

- Reoperation for isolated tricuspid valve repair or replacement for persistent symptoms due to severe tricuspid regurgitation (stage D) in members who have undergone previous left-sided valve surgery and who do not have severe pulmonary hypertension or significant right ventricular systolic dysfunction.

Pregnancy and valvular heart disease.

- Valve repair or replacement before pregnancy for symptomatic female members with severe valve regurgitation.

Coronary artery disease.

- Coronary artery bypass graft or percutaneous coronary intervention in members undergoing valve repair or replacement with significant coronary artery disease (≥70% reduction in luminal diameter in major coronary arteries or ≥50% reduction in luminal diameter in the left main coronary artery).

Limitations

Heart valve tissue engineering based on decellularized xenogenic or allogeneic starter matrices are investigational/not clinically proven, and, therefore, not medically necessary (Weber, 2013).

Alternative covered services

Prosthetic cardiac valve implantation.

Background

The aortic valve, one of four valves in the heart that maintain proper blood flow, delivers blood from the heart to the body. The valve may not function properly, either as a congenital defect or one that develops later in life. Various types of aortic valve disease are known. The valve may not close properly; among the most common heart valve disorders are regurgitation (blood leaking backward to the left ventricle) and stenosis (narrowed valve). Rates are increasing because of the growing elderly population, which have higher prevalence of heart valve disease (Vahanian, 2011).

Symptoms of aortic valve disease include heart murmur, shortness of breath, dizziness, fainting, chest pain or tightness, irregular heartbeat, fatigue or reduced activity, and swelling of the feet and ankles. Children may not eat enough and not gain enough weight. Aortic valve disease raises the risk of stroke, blood clots, and heart rhythm abnormalities (Mayo Clinic, 2020).

Valvular heart disease is frequently undiagnosed. A large-scale screening program increased the prevalence of valvular heart disease among the elderly by 51%, with a predicted 122% increase by the year 2014 (d'Arcy, 2016).

An estimated 182,000 heart valve transplants are conducted in the United States each year, which is expected to increase to over 240,000 by 2026 (iDataResearch, 2020). The most common treatment for end-stage valvular heart diseases is surgical replacement by either mechanical or bioprosthetic heart valves. Bioprosthetic heart valve replacements are either of animal origin (xenografts) or taken from human donors (homografts). Cryopreserved donor valves are the heart valve replacements closest to the natural valve, being non-thrombogenic and having a low risk of infection.

An emerging trend in treatment of aortic stenosis by transcatheter approaches (transfemoral, transapical) has created a body of evidence regarding the efficacy and safety of minimally invasive implantation of a mechanical prosthetic versus open-surgical transplantation of tissue. In general, patients who are younger (i.e., < 60 years of age) and who can tolerate lifetime anticoagulation medication may benefit more from a minimally invasive mechanical device implantation than a bioprosthetic.

Over time, several types of new, less invasive procedures have become available to surgically transplant heart valves. Two of these are transcatheter aortic valve replacement and sutureless aortic valve replacement, which are now used more frequently than the traditional surgical methods (Shinn, 2018).

The Ross 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. Ross sought to attain a balance between a more complicated surgical procedure (essentially a double valve replacement) and a potentially more durable and physiologic aortic valve replacement. It is thought that the autografted pulmonary valve will grow with the young patient, thus obviating the need for re-operation. Ross is now being used more frequently than other mechanical and homograft aortic valve replacement (Etnel, 2016).

Findings

An American College of Cardiology/American Heart Association Task Force published guidelines for the management of patients with valvular heart disease — including criteria for heart valve transplantation — that form the basis of the criteria in the coverage section of this policy (Nishimura, 2014). The same team updated the guidelines several years later (Nishimura, 2017). Another subsequent American College of Cardiology guideline endorsed the 2014 version's criteria, adding that valve repair is preferable to valve replacement when technically feasible (Stout, 2019).

In February 2021, the American College of Cardiology/American Heart Association published an update to its earlier guidelines. It included no new indications for revascularization from prior versions, but did address indications for managing coronary artery disease after revascularization (Otto, 2021).
The European Society of Cardiology also has guidelines for when heart valve transplant should be considered, including:

- In symptomatic patients with left ventricular ejection fraction and low-flow, low-gradient aortic stenosis (valve area less than 1 cm^2, fraction less than 40%, mean pressure gradient less than 40 mm Hg), low-dose dobutamine stress echocardiography should be considered to identify those with severe aortic stenosis suitable for valve replacement.
- Patients with severe aortic stenosis who are not suitable for surgery as assessed by a "heart team" and have predicted post-transcatheter aortic valve implantation survival greater than one year.
- Patients fit for surgery with severe aortic regurgitation (all symptomatic and asymptomatic patients with resting left ventricular ejection fraction up to 50% (Ponikowski, 2016).

The Centers for Medicare & Medicaid Services has issued a National Coverage Determination with medical indications for transcatheter aortic valve transplants (Centers for Medicare & Medicaid Services, 2019).

Meta-analyses and systematic reviews comparing transcatheter and surgical replacements found mostly mixed results, with the others showing superior results for transcatheter procedures:

- In patients with advanced kidney disease, those undergoing transcatheter replacement had significantly reduced risk of various outcomes. These include in-hospital mortality (47% lower), stroke (32% lower), acute kidney injury (58% lower), bleeding (65% lower), and infection (77% lower) (Wei, 2021).
- 16 studies (n = 13,310) showed patients with transcatheter valve replacement had significantly lower incidence of atrial fibrillation, myocardial infarction, and cardiogenic shock. Rates were significantly higher after transcatheter procedures for permanent pacemaker procedures, major vascular complications, neurological events, and transient ischemic attacks (Ding, 2021).
- 16 studies (n = 14,394) showed transcatheter implantation and surgical replacement had similar mortality rates up to five years after the procedure. After 30 days, the transcatheter approach had lower rates of myocardial infarction, cardiogenic shock, acute kidney injury, and new-onset atrial fibrillation, but higher rates of pacemaker implantation and major vascular complications (Zhao, 2021).
- 21 studies (n = 12,467) revealed transcatheter patients at low surgical risk had a lower mortality at one year, but not two years; transcatheter and surgical patients at intermediate risk had similar mortality. Risk of myocardial infarction and stroke were similar, but transcatheter procedures had a higher incidence of reintervention, major vascular complication, and paravalvular leak (Lou, 2020).
- 8 randomized controlled trials (n = 8,040), 41.4% of whom were female, showed a significantly lower rate in females for the transcatheter group for one-year mortality (12.2% vs 17.7%), but not five-year mortality. Women in the transcatheter group had lower rates of major bleeding and acute kidney injury, which were similar for both groups in men (Dagan, 2020).
- 12 studies (n = 27,956) for persons at low surgical risk revealed short-term total mortality plus short-term and one-year cardiac mortality were significantly lower in the transcatheter group. One-year total mortality, short-term, and 1-year stroke and myocardial infarction were similar (Vipparthy, 2020).
- 13 randomized controlled trials indicated transcatheter valves had more paravalvular regurgitation, moderate/severe aortic regurgitation, and reintervention after 1, 2-3, and 5 years (each $P < .00001$). Authors agree valves in transcatheter procedures are more likely to deteriorate structurally (Ler, 2020).
- 7 studies (n = 8,221) of patients with severe aortic stenosis and a history of cardiac surgery found the transcatheter group had lower rates of stroke and bleeding. No significant difference between groups was observed in terms of AKI, 30-day mortality, and 1-2-year mortality. Average procedure time and duration of hospital stay were shorter ($p < 0.01$) in the transcatheter group (Latif, 2020).
- 7 randomized controlled trials (n = 6,929) of patients with aortic stenosis associated with a high surgical risk revealed a significantly higher risk of transient ischemic attack ($P = .029$), and permanent pacemaker implantation (< .001) in the transcatheter group. However, lower rates of post-procedural bleeding ($P = .042$), new-onset or worsening of atrial fibrillation ($P < .001$), acute kidney injury ($P < .001$), and cardiogenic shock ($P < .001$) were found in the transcatheter group. Risk of aortic-valve re-intervention at one and two year in low/intermediate surgical risk patients were significantly higher in the transcatheter group (P = .005 and P = .001) (Zhang, 2020).
- 19 studies (n = 84,288) patients showed no significant difference between groups in rates of prosthetic valve endocarditis after 30 days ($P = 0.41$), one year ($P = 0.84$), two years ($P = 0.92$) and five years ($P = 0.81$) (Ullah, 2020).

Other systematic reviews and meta-analyses provided outcome measures of heart valve transplants according to the type of procedure (Ross, other mechanical, homograft), with Ross having the most positive results:

- A systematic review/meta-analysis 23 studies (n = 6,278 adults) undergoing the Ross procedure found survival rates of 95.6%, 91.8%, 86.3% and 80.5% at five, ten, fifteen and twenty years (Flynn, 2021).
- A systematic review/meta-analysis of 34 studies and 42 cohorts (n = 3,105 children) followed aortic valve replacement patients for an average of 6.6 years. Compared with other mechanical aortic valve

replacement and homograft aortic valve replacement, patients with the Ross procedure had

significantly lower early mortality rates (4.20% versus 7.34% and 12.82%) and lower late mortality rates (0.64% versus 1.23% and 1.59%) (Etnel, 2016).

- Another systematic review/meta-analysis of 15 studies (n = 5,346) showed persons undergoing the Ross procedure had decreased late mortality, compared with the other two methods (McClure, 2019).
- A systematic review/meta-analysis of 15 studies (two randomized controlled) included 1,412 patients who underwent aortic valve replacement. Patients with Ross procedure had a lower (superior) mean aortic gradient at discharge and latest follow-up, significant for both at $P < .0001$. No significant difference was observed in the incidence of severe aortic regurgitation at latest follow-up between patients undergoing the Ross procedure and those having other procedures (Um, 2018).
- A systematic review/meta-analysis of 18 studies (n = 3,516) of young and middle-age adults, followed patients for a median of 5.8 years. Patients undergoing the Ross procedure compared with other mechanical procedures had a 46% lower all-cause mortality ($P = .004$), 74% lower stroke rate ($P = .02$), and 83% lower major bleeding rate ($P < .001$), but a 76% higher rate of re-intervention (Mazine, 2018).
- A meta-analysis of 63 articles (n = 19,155) showed Ross procedure mortality was 2.5%, clinically significant bleeding was 1.0%, and re-exploration for bleeding was 4.6%. Long-term outcomes include mortality of 5.9% (mean follow-up 7.2 years); risk of valve thrombosis 0.3% (7.6 years); peripheral embolism 0.3% (6.4 years); stroke 0.9% (6.5 years); and endocarditis 2.1% (8.0 years) (Sibilio, 2019).

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On September 14, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "heart valve transplant," “Ross procedure,” “sutureless aortic valve replacement,” “transcatheter aortic valve replacement,” "valve allograft," and "prosthetic heart valve." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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