CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0227

Subject **Balloon Valvuloplasty**

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Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE
*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA*

Coverage Policy

CIGNA covers percutaneous balloon valvuloplasty as medically necessary for aortic stenosis when ANY of the following criteria are met:

- adolescent or young adult with symptoms of angina, syncope or dyspnea on exertion, and a catheterization peak gradient ≥ 50 millimeters of mercury (mm Hg), without a heavily calcified valve
- asymptomatic adolescent or young adult with catheterization peak gradient > 60 mm Hg
- asymptomatic adolescent or young adult with ST or T-wave changes over the left precordium on electrocardiogram (ECG) at rest or with exercise, with a catheterization peak gradient > 50 mm Hg
- asymptomatic adolescent or young adult with catheterization peak gradient is > 50 mm Hg who is considered to be at high risk because of a potential sustained high cardiac output state (e.g., pregnancy)
- as a bridge to surgery in hemodynamically unstable adult individual at high risk for surgical aortic valve replacement (AVR)
- as palliation in an adult in whom AVR cannot be performed because of serious comorbid conditions
- infant or child with well-formed bicuspid valves and an aortic annulus of sufficient size

CIGNA covers percutaneous balloon valvuloplasty as medically necessary for mitral stenosis (MS) when ANY of the following criteria are met:

- symptomatic individual with New York Heart Association (NYHA) functional class II, III, or IV, with moderate to severe MS and favorable valve morphology, in the absence of left atrial thrombus or moderate to severe mitral regurgitation
- asymptomatic individual with moderate to severe MS and favorable valve morphology who has pulmonary hypertension, in the absence of left atrial thrombus or moderate to severe mitral regurgitation
- individual with moderate to severe MS, with non-pliable, calcified valve, in NYHA functional class III-IV and a non-pliable valve, who is not a candidate for surgery or is at high risk for surgery

CIGNA covers percutaneous balloon valvuloplasty as medically necessary for pulmonary valve stenosis when EITHER of the following criteria is met:

- adolescent or young adult with exertional dyspnea, angina, syncope or presyncope and a catheterization peak gradient > 30 mm Hg
- asymptomatic adolescent or young adult with catheterization peak gradient > 40 mm Hg

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General Background

Percutaneous balloon valvuloplasty is a procedure that emerged in the 1980s as an alternative to open surgical valve repair. In balloon valvuloplasty, also called balloon valvotomy, one or more balloons are placed across a stenotic valve under radiological guidance and inflated in order to decrease the severity of stenosis. Percutaneous balloon valvuloplasty is used primarily to treat stenosis of the aortic, mitral and pulmonary valves.

Aortic Stenosis
Aortic stenosis may be congenital or may develop as a result of rheumatic fever. The most common cause of aortic stenosis in adults is an idiopathic degenerative calcification process that progresses from the base of the cusps to the leaflets, reducing the effective valve area. Aortic stenosis increases the afterload of the left ventricle, resulting in left ventricular (LV) hypertrophy. Symptoms may include angina, dyspnea, syncope or palpitations. Standard surgical treatment generally involves sternotomy with either valvotomy or valve replacement. Percutaneous balloon valvuloplasty has a significant role in the treatment of aortic stenosis in adolescents and young adults, but its role in treating older adults is limited. The mechanism of relief of the stenotic lesion in older adults is based on the fracturing of calcific deposits within the valve leaflets, and, to a lesser extent, stretching of the annulus and separation of the calcified or fused commissures. Immediate hemodynamic results include moderate reduction in the transvalvular pressure gradient and improvement of symptoms, although the increase in valve area is generally modest. Serious complications are frequent, however, occurring in more than 10% of cases, and restenosis and clinical deterioration occur in most patients within six to twelve months. Overall, balloon valvuloplasty has not reduced the high mortality seen in patients who do not undergo surgery for symptomatic aortic stenosis. Early enthusiasm for mitral valvuloplasty in the treatment of adults has waned considerably because of these factors. Balloon valvuloplasty is not considered a substitute for aortic valve replacement (AVR) in adults.

Despite procedure-related morbidity and mortality and limited long-term results, balloon valvuloplasty is sometimes used as a bridge to surgery in symptomatic patients who are not currently candidates for surgery, such as those with refractory pulmonary edema, cardiogenic shock, or other complicating medical problems. Valvuloplasty may also be performed as palliative treatment in patients for whom AVR cannot be recommended because of serious comorbid conditions. (Libby, 2007; Topol, 2007; Bonow, et al., 2006)

Balloon valvuloplasty has been shown to be much more effective in treating aortic stenosis in adolescents and young adults than in adults. While aortic stenosis in adults stems primarily from calcium build-up, in adolescents and young adults it usually results from fusion of commissures. Treating this condition with balloon valvuloplasty in adolescents and young adults has demonstrated positive mid-term results. In one large, collaborative registry involving 606 patients from 23 institutions, the peak pressure gradients at catheterization were reduced by a mean of 60%. In a single-institution study of 148 patients who received balloon valvuloplasty at age one month to 20 years, eight-year survival was reported at 95%, with three of the four deaths occurring in infants dilated at less than one year. Eight years after the procedure, 70% of patients treated had not required operation, and 50% had required no intervention. These results are comparable to those of open repair (Bonow, et al., 2006).

Congenital aortic stenosis is a fairly common abnormality, representing 8–10% of all infants and children with congenital heart disease. The condition may be associated with coarctation of the aorta, pulmonary stenosis, mitral valve abnormalities, patent ductus arteriosus and ventricular septal defect. Severe neonatal aortic stenosis results in disorganization of the valve with complete or partial absence of one or more of the commissures and requires urgent intervention. Either balloon valvuloplasty or surgical valvotomy using cardiopulmonary bypass may be performed. Balloon valvuloplasty has been most successful in children with well-formed bicuspid valves and aortic annuli of sufficient size. The degree of long-term success depends on effective balloon dilatation of the valve, as well as the diagnosis of left heart hypoplasia (Walsh, 2003; Yacoub, 2004).

The National Institute for Clinical Excellence (NICE) issued Interventional Procedure Guidance on balloon valvuloplasty in July 2004, stating that current evidence on the safety and efficacy of balloon valvuloplasty for aortic valve stenosis in adults and children appears adequate to support the use of this procedure. The NICE guidance further stated that, in adults, the procedure should only be used to treat patients who are unsuitable for surgery, as the efficacy is usually short-lived.

The American College of Cardiology/American Heart Association (ACC/AHA) published updated guidelines for the management of patients with valvular heart disease (Bonow, et al.) in 2006. Recommendations are classified as follows:

- Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful and effective.
- Class II: conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
    - Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
    - Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

The current ACC/AHA guideline on the management of patients with valvular heart disease provides the following recommendations for balloon valvuloplasty in patients with aortic stenosis:

Class I:

- adolescent or young adult with symptoms of angina, syncope and dyspnea on exertion, and a catheterization peak gradient ≥ 50 mm Hg without a heavily calcified valve
- asymptomatic adolescent or young adult with catheterization peak gradient > 60 mm Hg
- asymptomatic adolescent or young adult with ST or T-wave changes over the left precordium on ECG at rest or with exercise, with a catheterization peak gradient > 50 mm Hg

Class IIa

- asymptomatic adolescent or young adult when catheterization peak gradient is > 50 mm Hg and the patient wants to play competitive sports or wants to become pregnant
- balloon valvuloplasty is probably recommended over valve surgery in adolescents and young adults when the procedure is possible, and patients should be referred to a center with expertise in this procedure

Class IIb:

- as a bridge to surgery in hemodynamically unstable adult patient at high risk for AVR
- as palliation in an adult patient in whom AVR cannot be performed because of serious comorbid conditions

Class III

- should not be performed when catheterization peak gradient is < 40 mm Hg without symptoms or ECG changes

The ACC/AHA guideline does not evaluate indications, or include recommendations for valvuloplasty for infants and children.

Mitral Valve Stenosis

Mitral stenosis is an obstruction to the left ventricle inflow at the level of the mitral valve. The condition results from a structural abnormality of the mitral valve that prevents proper opening during diastolic filling of the left ventricle. Congenital mitral valve malformation is rare, and the current accepted surgical treatment is open

repair. Rheumatic carditis is the most frequent cause of mitral stenosis, occurring in 40% of patients presenting with rheumatic heart disease. A history of rheumatic fever is noted in approximately 60% of patients with mitral stenosis. In patients with mitral stenosis due to rheumatic fever, the leaflets thicken and calcify, and commissural and/or chordal fusion may occur, resulting in a funnel shape and decreased mitral opening size. Initial symptoms are dyspnea or atrial fibrillation with a rapid ventricular response. As stenosis increases, dyspnea increases; in addition, cardiac output decreases at rest and fails to increase during exercise.

Open mitral commissurotomy and replacement of the mitral valve has been the standard treatment for mitral valve stenosis. Percutaneous balloon mitral valvuloplasty, sometimes called percutaneous balloon commissurotomy, has become an alternative procedure in selected patients. Initial procedures used a double-balloon technique. Currently, the procedure is usually performed using a single hourglass-shaped (i.e., Inoue) balloon. The immediate results are comparable to mitral commissurotomy, with the procedure achieving success in 80–95% of patients. The underlying mitral valve morphology is the single greatest factor in determining outcome. Patients with valvular calcification, thickened fibrotic leaflets with decreased mobility and sub-valvular fusion have a greater incidence of acute complications and recurrent stenosis. In patients with non-calcified, pliable valves and no calcium in the commissures, the procedure has been shown to have a success rate of > 90%, complication rate of < 3%, and sustained improvement in 80–90% of patients over a three- to seven-year follow-up period (Bonow, 2006).

An analysis of 15 years of follow-up data confirmed the long-term efficacy of balloon mitral valvuloplasty in a large population with a variety of subsets (Vahanian, 2004). Percutaneous balloon valvuloplasty has become the procedure of choice for symptomatic patients with moderate to severe MS and favorable valve morphology and is a safe and effective alternative to surgical repair in these patients. Clinical improvement, complications and long-term durability of the outcome of balloon mitral valvuloplasty have been shown to be comparable to surgical commissurotomy in appropriately selected patients. In addition, if restenosis occurs, repeat balloon valvuloplasty or surgery can be performed without the difficulties and inherent risks resulting from pericardial adhesions and chest wall scarring (Vahanian and Palacios, 2004; Libby: Braunwald's Heart Disease, 2007).

The ACC/AHA 2006 guidelines for the management of patients with valvular heart disease provide the following recommendations for balloon valvuloplasty for the treatment of mitral stenosis:

Class I:
- symptomatic patient with moderate or severe MS and favorable valve morphology, in the absence of left atrial thrombus or moderate to severe mitral regurgitation
- asymptomatic patient with moderate or severe MS, with favorable valve morphology with pulmonary hypertension, in the absence of left atrial thrombus or moderate to severe mitral regurgitation

Class IIa:
- patient with moderate to severe MS, with non-pliable, calcified valve, in New York Heart Association (NYHA) functional class III-IV (see below), and who is not a candidate for surgery or is at high risk for surgery

Class IIb:
- asymptomatic patient with moderate or severe mitral stenosis and with favorable valve morphology with new onset atrial fibrillation in the absence of left atrial thrombus or moderate to severe mitral regurgitation
- symptomatic (NYHA functional class II, III, or IV) patient with mitral valve area > 1.5 cm^2 with evidence of hemodynamically significant mitral stenosis based on pulmonary artery systolic pressure ≥ 60 mm Hg, pulmonary artery wedge pressure ≥ 25 mm Hg, or mean mitral valve gradient >15 mm Hg during exercise
- patient with moderate to severe mitral stenosis, non-pliable calcified valve, in NYHA class III-IV, as an alternative to surgery

Class III
- not indicated for patients with mild mitral stenosis
- should not be performed in patients with moderate to severe mitral regurgitation or left atrial thrombus

NYHA Functional Classification:

Class I	No symptoms and no limitations in ordinary physical activity
Class II	Mild symptoms and slight limitation during ordinary activity; comfortable at rest

Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity; comfortable only at rest
Class IV Severe limitations; experiences symptoms even while at rest

Pulmonary Valve Stenosis
The pulmonary valve is the least likely to be affected by acquired heart disease. Pulmonary valve stenosis is almost exclusively a congenital disorder. Patients with pulmonary valve stenosis usually have a conical valve formed by fusion of the leaflets that project into the main pulmonary artery. Symptoms are unusual in children or adolescents, even when pulmonary valve stenosis is severe. Adults with longstanding, severe obstruction may experience dyspnea and fatigue when cardiac output does not increase adequately with exercise. Tricuspid regurgitation and right ventricular failure can occur with longstanding, severe obstruction in the neonate or adult. Balloon valvuloplasty has been the treatment of choice for the typical domed, thickened valve for both children and adults since the late 1980s. Surgical repair is still necessary for the dysplastic valve frequently associated with Noonan's syndrome (i.e., male Turner's syndrome). Early and mid-term results suggest outcomes for balloon valvuloplasty comparable to those for open valvotomy (Bonow, et al., 2006; Walsh, 2003).

Interventional Procedure guidance issued by NICE (2004) states that current evidence on the safety and efficacy of balloon dilatation of pulmonary valve stenosis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

The ACC/AHA 2006 guideline for the management of patients with valvular heart disease provides the following recommendations for balloon valvuloplasty for the treatment of pulmonic stenosis:

Class I
- adolescent and young adult patients with pulmonic stenosis with exertional dyspnea, angina, syncope or presyncope and catheterization peak gradient > 30 mm Hg
- asymptomatic adolescent and young adult patient with catheterization peak gradient > 40 mm Hg

Class IIb:
- asymptomatic adolescent or young adult patient with catheterization peak gradient of 30–39 mm Hg

Class III:
- not recommended in asymptomatic adolescent or young adult patient with catheterization peak gradient < 30 mm Hg

American Thoracic Society (ATS) American Association for Thoracic Surgery (AATS), and Society for Cardiovascular Angiography and Interventions (SCAI)
A joint position statement from the ATS, AATS, and SCAI on the clinical development of percutaneous heart valve technology states that, for selected patients with pulmonic or mitral stenosis, percutaneous valvuloplasty is the treatment of choice. For patients with calcific aortic stenosis, balloon aortic valvuloplasty has been used as a bridge to AVR as noted by current ACC/AHA guidelines. Hospital mortality for balloon valvuloplasty varies from 3.5%–13.5%, with as many as 25% of patients experiencing at least one serious complication. The durability of balloon valvuloplasty is limited. The statement concludes that open aortic valve replacement remains the definitive therapy for aortic stenosis in patients who are viable candidates for surgery.

Summary
Balloon valvuloplasty plays a significant role in the treatment of aortic stenosis in selected adolescents and young adults, with results comparable to those seen with open surgical repair. Balloon valvuloplasty is also an alternative to surgical repair for carefully selected infants and children with well-formed bicuspid valves and aortic annuli of sufficient size. The role of balloon valvuloplasty in the treatment of adults with aortic stenosis, however, is limited. This approach may be indicated in adults as a bridge to surgery in hemodynamically unstable patients who are at high risk for complications associated with AVR and may have a role in managing certain symptomatic patients who are not candidates for AVR.

Balloon valvuloplasty has become the procedure of choice for selected patients with moderate to severe mitral stenosis who have favorable valve morphology. This procedure has also become the procedure of choice for pulmonary valve stenosis in patients with the typical domed, thickened pulmonary valve.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
92986	Percutaneous balloon valvuloplasty; aortic valve
92987	Percutaneous balloon valvuloplasty; mitral valve
92990	Percutaneous balloon valvuloplasty; pulmonary valve

ICD-9-CM Diagnosis Codes	Description
394.0	Mitral stenosis
394.2	Mitral stenosis with insufficiency
395.0	Rheumatic aortic stenosis
395.2	Rheumatic aortic stenosis with insufficiency
396.0	Mitral valve stenosis and aortic valve stenosis
396.1	Mitral valve stenosis and aortic valve insufficiency
396.2	Mitral valve insufficiency and aortic valve stenosis
396.8	Multiple involvement of mitral and aortic valves
746.02	Congenital stenosis of pulmonary valve
746.3	Congenital stenosis of aortic valve
747.22	Congenital atresia and stenosis of aorta
747.3	Congenital anomalies of pulmonary artery

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	01/15/2008	0227	Balloon Valvuloplasty