Policy

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

I. Aetna considers percutaneous balloon dilation (valvuloplasty) of severe rheumatic mitral valve stenosis medically necessary in members who meet any of the following:

A. Members in the 2nd and 3rd trimesters of pregnancy in whom balloon valvuloplasty would be expected to achieve hemodynamic and symptomatic improvement with minimal risk to the mother and fetus, or

B. Members with favorable valve anatomy and a cumulative score of 8 or less on echocardiographic criteria (see below), or

C. Members with mitral valve re-stenosis after previous open surgical commissurotomy; or

D. Members with unfavorable valve anatomy who are poor surgical candidates because of medical co-morbidities or refuse surgery.
II. Aetna considers percutaneous balloon dilation of severe aortic valve stenosis medically necessary in members who meet any of the following:

A. As a "bridge" to aortic valve replacement in members with severe heart failure who are at extremely high operative risk, or
B. For palliative use in children with congenital critical aortic valve stenosis, until the child is old enough to have a valve replacement; or
C. Members in the 2nd and 3rd trimesters of pregnancy with critical aortic stenosis, or
D. Members who are not candidates for surgical valve replacement because of medical co-morbidities, but in whom balloon valvuloplasty would be expected to palliate severe symptoms or stabilize cardiogenic shock, or
E. Members with critical aortic stenosis who have an absolute surgical contraindication or refuse surgical treatment; or
F. Members with severe aortic stenosis who must undergo an urgent non-cardiac operation (e.g., gastrointestinal bleeding) and whose surgical risk would be reduced with the improvement in hemodynamic status afforded by balloon valvuloplasty.

III. Aetna considers percutaneous balloon dilation medically necessary for pulmonary valve stenosis.

IV. Aetna considers percutaneous balloon dilation experimental and investigational for all other indications because of insufficient evidence of safety and effectiveness.

V. Aetna considers balloon aortic valvuloplasty for selection of proper transcatheter heart valve (THV) size in persons undergoing THV implantation experimental and investigational because its effectiveness for this indication has not been established.

VI. Aetna considers percutaneous balloon valvuloplasty for bioprosthetic tricuspid valve stenosis experimental and investigational because of insufficient evidence of safety and effectiveness.
Background

The technique of balloon valvuloplasty (also called valvotomy or commissurotomy) involves the percutaneous transcatheater insertion of 1 or more large balloons into the aortic and/or mitral valve. The balloons are then inflated across the stenotic valve in order to decrease the degree of obstruction within the valve.

Balloon mitral commissurotomy (BMC) has become the procedure of choice for the treatment of adult patients with rheumatic mitral stenosis. Recent studies have shown that the long-term results of BMC are superior to open surgical commissurotomy in patients who have favorable mitral valve anatomy as determined by echocardiographic examination. Criteria have been developed to identify which patients with symptomatic mitral stenosis are most likely to benefit from balloon valvuloplasty. The valve is assessed on the basis of 4 characteristics, each of which is graded on a scale from 0 to 4 (favorable to unfavorable): (i) leaflet mobility; (ii) valvular thickening; (iii) subvalvular thickening; and (iv) valvular calcification. Good procedural results have been obtained with echocardiographic scores of 8 or less, that is the valve characteristics include a pliable, non-calcified valve with mild subvalvular disease and no or mild mitral regurgitation.

Aortic balloon valvuloplasty in adults with calcific aortic stenosis has been fraught with short-lived hemodynamic benefit and high rates of re-stenosis. Despite disappointing intermediate-term (6 to 12 months) results, the procedure does have its role in the management of critical aortic stenosis in patients who are not surgical candidates.

Balloon valvuloplasty has been used in children with congenital critical aortic stenosis, until the child is old enough to have valve replacement (NICE, 2004). A comparative study involving 110 neonates with critical aortic stenosis found the mean reduction in systolic gradient to be 65 % for neonates treated with balloon valvuloplasty, compared to 41 % for neonates treated with open surgery (McCrindle et al, 2001). Aortic regurgitation rates were 18 % (15/82) in the balloon valvuloplasty group compared with 3 % (1/28) in the open surgery group. Immediate major complications were reported in 4 % (3/82) of the balloon valvuloplasty group and 0 % (0/28) of the open surgery group.

Pulmonary valve stenosis is a congenital heart defect in which
blood flow from the heart to the pulmonary artery is blocked. Symptoms include cyanosis, fainting, fatigue, chest pains, shortness of breath, poor weight gain or failure to strive in infants, and, in some instances, sudden death. If the stenosis is severe, the pulmonary valve must be opened to increase blood flow to the lungs. Based upon limited evidence from published case series, the National Institute for Health and Clinical Excellence (NICE) concluded that percutaneous balloon valvuloplasty is an established alternative to open surgical valvotomy for pulmonary valve stenosis (NICE, 2004).

Trans-esophageal echocardiogram (TEE) measurement alone of the aortic annulus may not be adequate to select a transcatheter heart valve (THV) size. Balloon aortic valvuloplasty (BAV) can more accurately size the aortic annulus. Babaliaros et al (2010) described the use of BAV to select proper THV size in patients undergoing THV implantation. A total of 27 patients underwent sizing of the aortic annulus by BAV and TEE. These researchers implanted the minimal THV size that was greater than the annulus measured by BAV. The annulus measured by TEE was 21.3 +/- 1.6 mm and by BAV was 22.6 +/- 1.8 mm (p < 0.001). The number of balloon inflations was 2.7 +/- 0.7 (range of 2 to 4), and the balloon sizes used were 22.0 +/- 1.8 mm (range of 20 to 25 mm). Fourteen patients (52 %) required up-sizing of the initial balloon suggested by TEE; rapid pacing duration was 8 +/- 1.3 s (range of 6 to 11 s). No change in aortic insufficiency or hemodynamic instability occurred with BAV. Fifteen patients (56 %) received a 23-mm THV; 12 patients a 26-mm THV. No coronary occlusion, annular damage, or THV embolization occurred. Para-valvular leak was grade less than or equal to 1 in all patients. In 7 patients (26 %), balloon sizing resulted in selection of a specific THV size that could not be done by TEE alone. The authors concluded that BAV sizing of the aortic annulus is safe and is an important adjunct to TEE when selecting THV size. Implanting the minimal THV greater than the BAV annulus size resulted in no adverse events. These findings suggested that use of BAV for THV selection may improve the safety and effectiveness of THV implantation. These preliminary findings need to be validated by well-designed studies.
Singh et al (2015) stated that the use of percutaneous aortic balloon valvotomy (PABV) in high surgical risk patients has resurged because of development of less invasive endovascular therapies. These investigators compared outcomes of concomitant PABV and percutaneous coronary intervention (PCI) with PABV alone during same hospitalization using nation's largest hospitalization database. They identified patients and determined time trends using the International Classification of Diseases, Ninth Revision, Clinical Modification, procedure code for valvulotomy from Nationwide Inpatient Sample database 1998 to 2010. Only patients greater than 60 years with aortic stenosis were included. Primary outcome included in-hospital mortality, and secondary outcomes included procedural complications, length of stay (LOS), and cost of hospitalization. A total 2,127 PABV procedures were identified, with 247 in PABV + PCI group and 1,880 in the PABV group. Utilization rate of concomitant PABV + PCI during same hospitalization increased by 225 % from 5.1 % in 1998 to 1999 to 16.6 % in 2009 to 2010 (p < 0.001). Overall in-hospital mortality rate and complication rates in PABV + PCI group were similar to that of PABV group (10.3 % versus 10.5 % and 23.4 % versus 24.7 %, respectively). PABV + PCI group had similar LOS but higher hospitalization cost (median [interquartile range] $30,089 [$21,925 to $48,267] versus $18,421 [$11,482 to $32,215], p < 0.001) in comparison with the PABV group. Unstable condition, occurrence of any complication, and weekend admission were the main predictors of increased LOS and cost of hospital admission. The authors concluded that concomitant PCI and PABV during the same hospitalization are not associated with change in in-hospital mortality, complications rate, or LOS compared with PABV alone; however, it increases the cost of hospitalization.

Percutaneous Balloon Valvuloplasty for Bioprosthetic Tricuspid Valve Stenosis:

Rana and colleagues (2017) noted that percutaneous transcatheter tricuspid balloon valvuloplasty (PTTBV) is an accepted treatment option for symptomatic severe native tricuspid valve stenosis, although surgical tricuspid valve replacement remains the treatment of choice. There have been
few reports of successful PTTBV for bioprosthetic tricuspid valve stenosis. These researchers presented case reports of 3 patients from their hospital experience; 2 of the 3 cases were successful, with lasting clinical improvement, whereas the 3rd patient failed to show a reduction in valve gradient. These investigators described the standard technique used for PTTBV, and presented results from a literature review that identified 16 previously reported cases of PTTBV for bioprosthetic severe tricuspid stenosis, with overall favorable results. The authors concluded that PTTBV should perhaps be considered for a select patient population in which symptomatic improvement and hemodynamic stability are desired immediately, and particularly for patients who are inoperable or at high surgical risk.

The authors stated that there have been no randomized controlled trials (RCTs) to prove the effectiveness of PTTBV. Although these case reports suggested that PTTBV for stenosis of bioprosthetic TVs is effective and is associated with low morbidity, isolated case reports almost certainly carry a degree of publication bias. It is conceivable that PTTBV has been performed in a multitude of patients who had less favorable results, reports of which were not presented or not accepted for publication. One of the 3 patients in this study failed to gain hemodynamic or symptomatic benefit from the procedure. They stated that further evidence is needed before PTTBV can be recommended as a frontline therapy for such patients; in the meanwhile, surgical correction of stenosed bioprosthetic valves remains the preferred method of treatment.

### 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 "+":**

**Percutaneous balloon dilation of severe rheumatic mitral stenosis:**

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<thead>
<tr>
<th>CPT codes covered if selection criteria are met:</th>
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<tbody>
<tr>
<td>92987</td>
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<table>
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<tr>
<th>Other CPT codes related to the CPB:</th>
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<tbody>
<tr>
<td>33476</td>
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<tr>
<td>Code</td>
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<td>33478</td>
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<td>93303 - 93350</td>
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**ICD-10 codes covered if selection criteria are met:**

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>I05.0</td>
<td>Rheumatic mitral stenosis</td>
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<tr>
<td>I05.2</td>
<td>Rheumatic mitral stenosis with insufficiency</td>
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<tr>
<td>I08.0</td>
<td>Rheumatic disorders of both mitral and aortic valves</td>
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<tr>
<td>I08.8</td>
<td>Other rheumatic multiple valve diseases</td>
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<tr>
<td>O99.412 - O99.413</td>
<td>Diseases of the circulatory system complicating pregnancy, 2nd or 3rd trimester</td>
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**Percutaneous balloon dilation of severe aortic stenosis:**

**CPT codes covered if selection criteria are met:**

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<th>Description</th>
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<td>33405 - 33413</td>
<td>Replacement of aortic valve</td>
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<tbody>
<tr>
<td>I06.0</td>
<td>Rheumatic aortic stenosis</td>
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<td>I06.2</td>
<td>Rheumatic aortic stenosis with insufficiency</td>
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<td>I08.8</td>
<td>Other rheumatic multiple valve diseases</td>
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<td>I35.0 - I35.9</td>
<td>Nonrheumatic aortic valve disorders</td>
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<tr>
<td>I70.0</td>
<td>Atherosclerosis of aorta</td>
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<td>Q23.0</td>
<td>Congenital stenosis of aortic valve</td>
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<td>Q25.21 - Q25.4</td>
<td>Congenital malformations of great arteries</td>
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**Percutaneous balloon dilation of pulmonary valve:**

**CPT codes covered if selection criteria are met:**

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<th>Description</th>
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<tr>
<td>92990</td>
<td>Percutaneous balloon valvuloplasty; pulmonary valve</td>
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**ICD-10 codes covered if selection criteria are met:**

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<th>Code</th>
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<tr>
<td>I09.89</td>
<td>Other specified rheumatic heart diseases</td>
</tr>
<tr>
<td>I37.0 - I37.9</td>
<td>Nonrheumatic pulmonary valve disorders</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:

22. Berger M. Natural history of mitral stenosis and


32. Rao PS. Percutaneous balloon pulmonary valvuloplasty:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number:
0477 Balloon Valvuloplasty

There are no amendments for Medicaid.