

POLICY TITLE	PERCUTANEOUS BALLOON VALVULOPLASTY
POLICY NUMBER	MP-2.031

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I. POLICY

Percutaneous balloon valvuloplasty may be considered **medically necessary** for treatment of patients with **mitral valve stenosis** who meet any of the following criteria:

- Symptomatic patients (NYHA functional Class II, III, or IV), with moderate or severe mitral stenosis and valve morphology favorable for percutaneous balloon valvotomy in the absence of left atrial thrombus or moderate to severe mitral regurgitation; or
- Asymptomatic patients with moderate or severe mitral stenosis, and valve morphology favorable for percutaneous balloon valvotomy who have pulmonary hypertension (pulmonary artery systolic pressure > 50 mm Hg at rest or 60mm Hg with exercise) in the absence of left atrial thrombus or moderate to severe mitral regurgitation; or
- Patients with NYHA functional Class III-IV symptoms, moderate or severe mitral stenosis, and a nonpliable calcified valve that are at high risk for surgery in the absence of left atrial thrombus or moderate to severe mitral stenosis.

Note: Moderate or severe mitral stenosis is defined as a mitral valve surface area $\leq 1.5\text{cm}^2$.

Pulmonic balloon valvuloplasty may be considered **medically necessary** for **pulmonary stenosis** in symptomatic patients or in patients with right ventricular to pulmonary artery peak gradient of 40mm Hg or greater.

Percutaneous aortic balloon valvuloplasty may be considered **medically necessary** for adolescents and young adults in their early 20s with **aortic stenosis** who meet any one of the following criteria:

- Symptoms of angina, syncope, and dyspnea on exertion, with catheterization peak gradient ≥ 50 mm Hg;
- Catheterization peak gradient > 60mm Hg;
- New-onset ischemic or repolarization changes on EKG at rest or with exercise (ST depression, T-Wave inversion over left precordium) with a gradient >50mm Hg; or
- Catheterization peak gradient >50mm Hg if patient wants to play competitive sports or desires to become pregnant.

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Percutaneous aortic balloon valvuloplasty for adult patients with **aortic stenosis** may be considered **medically necessary** as a bridge to surgery and in patients who are at high risk for aortic valve replacement.

Percutaneous balloon valvuloplasty for treatment of conditions other than those described in section III above is considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

[N] Capital Cares 4 Kids

[N] FEP PPO

[N] SeniorBlue HMO

[N] Indemnity

[N] SeniorBlue PPO

III. DESCRIPTION/BACKGROUND

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Balloon valvuloplasty is the dilation of a stenotic valve using a balloon-tipped catheter and imaging to visualize the stenotic valve. The balloon is inflated at the proper moment to dilate the stenotic valve. Percutaneous balloon valvuloplasty has been used in the treatment of stenosis of the pulmonic, mitral, and aortic valves.

When used in the treatment of a stenotic pulmonary valve, a balloon-tipped catheter is passed from the femoral or brachial vein into the right atrium and then into the outflow tract of the right ventricle, the site of the pulmonic valve. By puncturing the atrial septum, access can also be obtained for either the mitral or aortic valves. The femoral artery can also be used to avoid septal puncture in ballooning left heart valvular lesions (mitral, aortic).

Percutaneous balloon valvuloplasty of the mitral valve is an invasive procedure utilized for patients with severe uncomplicated mitral stenosis in whom the anatomical features of the valve are favorable.

Percutaneous balloon valvuloplasty of the aortic valve is utilized to treat congenital aortic stenosis. It is most commonly performed on neonates, infants, children, and young adults.

IV. RATIONALE

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This policy is based on 2006 guidelines published by the American College of Cardiology in conjunction with the American Heart Association. (1) The guidelines were based on a review of

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the literature and additional input from an expert panel. The panel assigned their policy statements to one of three categories as follows:

Class I: Conditions for which there is evidence and/or general agreement that given procedure is useful or effective.

Class II: Conditions for which there is conflicting evidence and a divergent opinion about the usefulness/efficacy of a procedure or treatment.

Ia. Weight of evidence/opinion is in favor of usefulness/efficacy

Ib. Usefulness/efficacy is less well established by evidence/opinion.

Class III. Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful and in some cases may be harmful.

For the purposes of this policy, all indications categorized as Class I or Class Ia are considered to be medically necessary indications

ACC/AHA guideline summary: Percutaneous mitral balloon valvotomy (PMBV) in mitral stenosis (MS)

Class I - There is evidence and/or general agreement that PMBV is effective in the following settings in patients with MS who have favorable valve morphology in the absence of left atrial thrombus or moderate to severe mitral regurgitation:
<ul style="list-style-type: none"> • Symptomatic patients with moderate or severe MS (mitral valve area ≤ 1.5 cm²).* • Asymptomatic patients with moderate or severe MS who have pulmonary hypertension (defined as pulmonary artery systolic pressure >50 mmHg at rest or >60 mmHg with exercise).
Class IIa - The weight of evidence or opinion is in favor of the usefulness of PMBV in the following setting:
<ul style="list-style-type: none"> • Patients with moderate or severe MS* who have a nonpliable, calcified mitral valve, have moderate to severe symptoms of heart failure (New York Heart Association [NYHA] class III to IV) and are not candidates for or at high risk from surgery.
Class IIb - The weight of evidence or opinion is less well established for the usefulness of PMBV in the following settings:
<ul style="list-style-type: none"> • Patients with asymptomatic moderate to severe MS* who have favorable valve morphology and new onset of atrial fibrillation in the absence of left atrial thrombus or moderate to severe mitral regurgitation. • Patients with symptoms of heart failure (NYHA class II to IV) who have a mitral valve area >1.5 cm² and evidence of hemodynamically significant MS as evidenced by a pulmonary artery systolic pressure ≥ 60 mmHg, a pulmonary artery wedge pressure ≥ 25 mmHg, or a mean mitral valve gradient ≥ 15 mmHg during exercise. • As an alternative to surgery for patients with moderate to severe MS* who have a nonpliable, calcified mitral valve and moderate to severe symptoms of heart failure (NYHA class III to IV)
Class III - There is evidence and/or general agreement that PMBV is not useful in in the following settings:
<ul style="list-style-type: none"> • Patients with mild MS. • Patients with MS who also have moderate to severe mitral regurgitation or left atrial thrombus.

* There may be variability in the measurement of mitral valve area; as a result, the mean transmitral gradient, pulmonary artery wedge pressure, and pulmonary artery pressure at rest or during exercise should also be taken into consideration.

Data from Bonow RO, Carabello BA, Chatterjee K, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing committee to revise the 1998 guidelines for the management of patients with valvular heart disease). *J Am Coll Cardiol* 2006; 48:e1.

V. DEFINITIONS

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New York Heart Association (NYHA) Class II refers to patients with cardiac disease, which results in slight limitation of physical activity. These patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.

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New York Heart Association (NYHA) Class III refers to patients with cardiac disease, which results in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

New York Heart Association (NYHA) Class IV refers to patients with cardiac disease, which results in the inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

STENOSIS is a constriction or narrowing of a passage or orifice.

VALVULOPLASTY refers to reconstructive or restorative surgery on a valve.

V. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VI. DISCLAIMER

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Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

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1. American Heart Association [Website]: <http://my.americanheart.org> Accessed April 11, 2014.
2. Bonow RO, Carabello B, de Leon AC Jr et al. Guidelines for the management of patients with valvular heart disease: executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 1998; 98(18):1949-84.
3. Bittl J. Natural history and treatment of pulmonic stenosis. In: *UpToDate Online Journal [serial online]*. Waltham, MA: UpToDate; updated March 23, 2014 [Website]: www.uptodate.com. Accessed April 11, 2014

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5. Cubeddu RJ, Palacios IF. Percutaneous techniques for mitral valve disease. Cardiol Clin. 2010;28(1):139-153
6. Gaasch H. Percutaneous aortic valvotomy In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated February 4, 2013. Website]: www.uptodate.com. Accessed April 11, 2014.
7. Gaasch H, and J. Carroll. Percutaneous mitral balloon valvotomy for mitral stenosis. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated , January 7, 2014 [Website]: www.uptodate.com. Accessed April 11, 2014. Himbert D. Percutaneous cardiac valvular interventions. Rev Prat. 2009;59(2):207-212 National Institute for Health and Clinical Excellence (NICE). Balloon dilatation for pulmonary valve stenosis. Interventional Procedure Guidance 67. London, UK: NICE; June 2004. Available at: <http://www.nice.org.uk/page.aspx?o=ipg067guidance>. Accessed April 11, 2014.
8. National Institute for Health and Clinical Excellence (NICE). Balloon valvuloplasty for aortic valve stenosis in adults and children. Interventional Procedure Guidance 78. London, UK: NICE; July 2004. Available at: <http://www.nice.org.uk/page.aspx?o=ipg078guidance>. Accessed April 11, 2014.
9. Song JK, Kim MJ, Yun SC, et al. Long-term outcomes of percutaneous mitral balloon valvuloplasty versus open cardiac surgery. J Thorac Cardiovasc Surg. 2010;139(1):103-110.
10. Taber's Cyclopedic Medical Dictionary, 19th edition.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®							
92986	92987	92990					

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ICD-9-CM Diagnosis Code*	Description
391.1	ACUTE RHEUMATIC ENDOCARDITIS
394.0	MITRAL STENOSIS
394.2	MITRAL STENOSIS WITH INSUFFICIENCY
395.0	RHEUMATIC AORTIC STENOSIS
396.0	MITRAL VALVE STENOSIS AND AORTIC VALVE STENOSIS
396.1	MITRAL VALVE STENOSIS AND AORTIC VALVE INSUFFICIENCY

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396.8	MULTIPLE INVOLVEMENT OF MITRAL AND AORTIC VALVES
417.8	OTHER SPECIFIED DISEASE OF PULMONARY CIRCULATION
424.1	AORTIC VALVE DISORDERS
424.3	PULMONARY VALVE DISORDERS
746.3	CONGENITAL STENOSIS OF AORTIC VALVE

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
I01.1	Acute rheumatic endocarditis
I05.0	Rheumatic mitral stenosis
I05.2	Rheumatic mitral stenosis with insufficiency
I06.0	Rheumatic aortic stenosis
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.8	Other rheumatic multiple valve diseases
I28.8	Other diseases of pulmonary vessels
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.8	Other nonrheumatic aortic valve disorders
I35.9	Nonrheumatic aortic valve disorder, unspecified
I37.0	Nonrheumatic pulmonary valve stenosis
I37.8	Other nonrheumatic pulmonary valve disorders
Q23.0	Congenital stenosis of aortic valve

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. POLICY HISTORY

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MP 2.031	CAC 4/27/04
	CAC 6/28/05
	CAC 7/25/06
	CAC 9/26/06
	CAC 9/25/07
	CAC 3/25/08
	CAC 3/31/09 Consensus

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	CAC 3/30/10 Consensus
	CAC 4/26/11 Consensus
	CAC 6/26/12 Consensus
	7/30/13 Admin coding review complete--rsb
	CAC 11/26/13 Consensus, no change to policy statements. References updated.
	CAC 5/20/14 Consensus review. No change to the policy statements. References updated. Rationale added. No coding changes.

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