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**Name of Policy:****Transcatheter Ablation of Septal Hypertrophy (TASH)**

Policy #: 005  
Category: Surgery

Latest Review Date: June 2009  
Policy Grade: **Effective June 29, 2011: Active Policy but no longer scheduled for regular literature reviews and updates.**

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## **Description of Procedure or Service:**

Hypertrophic cardiomyopathy is a complex cardiac disease associated with diverse clinical, morphologic, and pathophysiologic manifestations. However, one of the most characteristic abnormalities is a hypertrophied and nondilated left ventricle, which may impair diastolic filling. When the hypertrophy results in left ventricular outflow obstruction, dyspnea, angina, syncope, or the development of congestive heart failure may occur. Pharmacologic therapies include beta-blockers or calcium-channel blockers to decrease the heart rate with a consequent prolongation in diastole and increased passive ventricular filling. If medical therapy is insufficient to control symptoms, strategies to reduce the outflow obstruction may be considered. Surgical resection focuses on removing a small amount of myocardium at the base of the septum (myotomy-myomectomy). Dual-chamber pacing has also been explored as a means of decreasing the pressure gradient in the outflow tract, although results of randomized trials have been disappointing.

The transcatheter ablation of septal hypertrophy (TASH) is a non-surgical septal reduction procedure, which involves the injection of ethanol into the septal branches of the coronary arteries in order to produce an infarct. The infarcted tissues undergo scarring with subsequent thinning, which will result in decreasing of the outflow gradient. Many times heart block will occur and therefore, a pacemaker will be inserted frequently at the time of the procedure. The procedure is usually performed in conjunction with heart catheterization and imaging studies to verify the location of the injection of the ethanol.

TASH may also be referred to as ethanol septal ablation.

## **Policy:**

**Transcatheter Ablation of Septal Hypertrophy** or also known as **Non-Surgical Septal Reduction** meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for services rendered on or after 5/23/01 when the following coverage criteria are met.

1. Severely symptomatic patient with hypertrophic cardiomyopathy (HOCM)
2. Basal outflow gradient 50 mmHg or greater
3. NYHA Class III or IV
4. Unresponsive to medical therapy

**Non-Surgical Septal Reduction does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients including, but not limited to the following:

1. Individuals not meeting the coverage criteria listed previously
2. Individuals with contraindications related to the procedure or co-morbid conditions which would reduce the efficacy of the procedure

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**

“The transcatheter septal ablation for septal hypertrophy has been investigated as a minimally invasive alternative to open surgical myotomy/myomectomy procedures in severely symptomatic patients with ventricular outflow gradients related to hypertrophic cardiomyopathy.

Myotomy/myomectomy procedure supports that it is associated with marked symptomatic and cardiodynamic improvement. The perioperative mortality of 2-5% is reported with this procedure. The septal reduction procedure has a perioperative mortality rate from 2-4%. Post procedure complete heart block is common requiring a permanent implantation of a pacemaker in up to 20% of the patients. The intermediate outcomes comparing this procedure to the myotomy/myomectomy show that 14% of patients reported persistent angina and 20% reported dyspnea in a total of 38 patients who underwent surgery for HOCM”. (Ten Berg, et al)

McCulley et al reported, “50% improvement in symptoms in 90% of their patients and persistent symptoms in 10%”.

Mohr, et al reported, “..on a long term outcome of 15 patients who underwent surgery for refractory symptoms due to HOCM. Seventy-six percent of these patients were relieved from dyspnea and 83% had resolution of their anginal symptoms. The septal reduction results compare favorably to the reductions achieved after surgical myotomy/myomectomy avoiding the associated morbidity”.

”This procedure is reported to be an efficacious procedure with comparative low risks in selected patients with HOCM who have incapacitating symptoms while maintenance medical therapy is provided”. (Lakkis, et al)

No new studies were available on transcatheter ablation of septal hypertrophy that would alter the current policy statement for June 2007. In a June 2007 article by Keane et al, these authors report on their experience using percutaneous transvalvular endomyocardial septal cryoablation (PTESC) for treating left ventricular outflow tract (LVOT) obstruction in hypertrophic cardiomyopathy. When TASH is used to treat the HOCM, there is concern with regard to the arrhythmogenic potential of the resultant myocardial scar. This article reports on the use of PTESC. Only three patients were reported in this study. Two of the patients had an immediate reduction in the LVOT gradient. At six months, only one patient had a significant reduction in LVOT gradient. No adverse events were reported. The authors concluded that PTESC is feasible but did not provide a significant, sustained reduction in LVOT gradient in two of the three patients in this small series of HOCM. The recommendation from the authors was that further study is warranted to improve the consistency and duration of reduction in outflow gradient.

**June 2009 Update**

Kuhn et al in 2008 published the results of a 10-year follow-up of survival after transcatheter ablation of septal hypertrophy in hypertrophic obstructive cardiomyopathy. This study was to determine the impact of TASH on the survival of all patients with HOCM treated in a their institution. Six hundred forty-four patients were assessed in the 10 year period. This study also represented the largest available database on survival after TASH. Based on the results, in-hospital mortality has become very low. Cardiac survival during follow up was excellent; however, the well-known risk of sudden death is not completely eliminated. The authors would like longer follow-up time for definite evaluation of this relatively new therapeutic option in the management of HOCM.

Kwon et al in 2008 also sought to assess the outcomes of alcohol septal ablation (ASA) in high-risk patients. The preferred method of treatment is surgical myectomy in patients with symptomatic HOCM. For patients who are considered high-risk for surgery, ASA is performed. Fifty-five patients had ASA for a period of three years at the authors' institution. Their conclusions for patients with symptomatic HOCM and are at high risk for surgery, ASA is associated with symptomatic improvement and low short-term mortality; with long-term mortality only associated with older age at time of procedure. In these symptomatic patients, ASA is a viable option.

There is no change in the coverage statement of this policy.

**Key Words:**

Transcoronary ablation of septal hypertrophy (TASH); ethanol injection into the cardiac septum; non-surgical septal reduction; ethanol ablation of the cardiac septum, percutaneous transvalvular endomyocardial septal cryoablation, PTESC

**Approved by Governing Bodies:**

The FDA does not regulate specific surgical procedures. This procedure does not have special equipment, which would require FDA regulation.

**Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification requirements: Not applicable

**Current Coding:**

CPT Codes:           **93799**           Unlisted cardiovascular surgery

**Previous Coding:**

**0024T**           Non-surgical septal reduction therapy (e.g., alcohol ablation), for hypertrophic obstructive cardiomyopathy; with coronary arteriograms, with or without temporary pacemaker (**Code deletes effective July 1, 2007**)

**References:**

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2. Kuhn H, Lawrenz T, Lieder F, Leuner C, et al. Survival after transcatheter ablation of septal hypertrophy in hypertrophic obstructive cardiomyopathy (TASH): A 10 year experience. Clin Res Cardiol, April 2008; 97(4): 234-243.
3. Kwon DH, Kapadia SR, Tuzcu EM, et al. Long-term outcomes in high-risk symptomatic patients with hypertrophic cardiomyopathy undergoing alcohol septal ablation. JACC Cardiovasc Interv, August 2008; 1(4): 432-438.
4. McCully RB, Nishimura RA, Tajik AJ, et al. Extent of clinical improvement after surgical treatment for hypertrophic obstructive cardiomyopathy, circulation 1996; 94:467-71.
5. Mohr R, Schaff H, Danielson GK, et al. The outcome of surgical treatment for hypertrophic obstructive cardiomyopathy: experience over 15 years, Journal of Thoracic Cardiovascular Surgery, 1989; 97:666-74.
6. Runquist Lars H, Nielsen Christopher D, Killip Donna, et al. Electrocardiographic findings after alcohol septal ablation therapy for obstructive hypertrophic cardiomyopathy, The American Journal of Cardiology, November 1, 2002, Vol. 90, No. 9.
7. Sitges Marta, Shiota Takahiro, et al. Comparison of left ventricular diastolic function in obstructive hypertrophic cardiomyopathy in patients undergoing percutaneous septal alcohol ablation versus surgical myotomy/myectomy, The American Journal of Cardiology, April 1, 2003, Vol. 91, No. 7.
8. Ten Berg J, Surtorp MJ, Kanepen P, et al. Hypertrophic obstructive cardiomyopathy, initial results and long-term follow-up after morrow septal myectomy, circulation 1994; 94:467-71.

### **Policy History:**

Medical Review Committee, May 23, 2001

Medical Review Committee, March 2000

Medical Policy Group, June 2003

Medical Policy Group, June 2005 (1)

Medical Policy Group, June 2007 (1)

Medical Policy Group, June 2009 (1)

Medical Policy Group, June 29, 2011; Active Policy but no longer scheduled for regular literature reviews and updates.

Medical Policy Group, October 2013 (1): Removed ICD-9 Diagnosis and Procedure Codes

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*