BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Transcoronary Ablation of Septal Hypertrophy (TASH)

Policy #: 005
Category: Surgical

Latest Review Date: November 2020
Policy Grade: **Effective June 29, 2011, this is an active policy but is no longer being reviewed for peer clinical data updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after July 1, 2005:

Blue Advantage will treat **transcoronary ablation of septal hypertrophy** as a **covered** benefit 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

Blue Advantage will treat **non-surgical septal reduction** as a **non-covered** benefit and as **investigational** 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 Advantage 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 Advantage administers benefits based on the members' contract and 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.

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 reaction 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.

Transcoronary ablation of septal hypertrophy (TASH), (also known as ethanol septal ablation, alcohol septal ablation, or non-surgical septal reduction) 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. Heart block is a common complication of this procedure and a pacemaker may need to be inserted 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.

KEY POINTS:

A literature search was conducted through July 9, 2019.

Summary of Evidence
For individuals who have severely symptomatic hypertrophic cardiomyopathy and receive transcoronary ablation of septal hypertrophy, the evidence consists of retrospective and prospective studies. The primary outcomes include long term outcomes, safety, mortality, and overall survival. The studies show that in properly selected patients, TASH is a safe and efficacious procedure. A high success rate with a low complication rate has also been reported with this procedure. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements
American College of Cardiology Foundation and American Heart Association
In 2011, the ACCF and AHA published a guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy:

Recommendation	Class	LOE
Septal reduction therapy should be performed only by experienced operators in the context of a comprehensive HCM clinical program and only for the treatment of eligible patients with severe drug-refractory symptoms and LVOT obstruction. Eligible patients are defined by all of the following: a. Clinical: Severe dyspnea or chest pain (usually NYHA functional classes III or IV) or occasionally other exertional symptoms (such as syncope or near syncope) that interfere with everyday activity or quality of life despite optimal medical therapy. b. Hemodynamic: Dynamic LVOT gradient at rest or with physiologic provocation 50 mm Hg associated with septal hypertrophy and SAM of the mitral valve. c. Anatomic: Targeted anterior septal thickness sufficient to perform the procedure safely and effectively in the judgment of the individual operator	I	C
Consultation with centers experienced in performing both surgical septal myectomy and alcohol septal ablation is reasonable when discussing treatment options for eligible patients with HCM with severe drug-refractory symptoms and LVOT obstruction.	IIa	C
When surgery is contraindicated or the risk is considered unacceptable because of serious comorbidities or advanced age, alcohol septal ablation, when performed in experienced centers, can be beneficial in eligible adult patients with HCM with LVOT obstruction and severe drug-refractory symptoms (usually NYHA functional classes III or IV)	IIa	B
Alcohol septal ablation, when performed in experienced centers, may be considered as an alternative to surgical myectomy for eligible adult patients with HCM with severe drug-refractory symptoms and LVOT obstruction when, after a balanced and thorough discussion, the patient expresses a preference for	IIb	B

septal ablation		
The effectiveness of alcohol septal ablation is uncertain in patients with HCM with marked (i.e., >30 mm) septal hypertrophy, and therefore the procedure is generally discouraged in such patients.	IIb	C
Septal reduction therapy should not be done for adult patients with HCM who are asymptomatic with normal exercise tolerance or whose symptoms are controlled or minimized on optimal medical therapy.	III	C
Septal reduction therapy should not be done unless performed as part of a program dedicated to the longitudinal and multidisciplinary care of patients with HCM.	III	C
Mitral valve replacement for relief of LVOT obstruction should not be performed in patients with HCM in whom septal reduction therapy is an option.	III	C
Alcohol septal ablation should not be done in patients with HCM with concomitant disease that independently warrants surgical correction (e.g., coronary artery bypass grafting for CAD, mitral valve repair for ruptured chordae) in whom surgical myectomy can be performed as part of the operation.	III	C

U.S. Preventive Services Task Force Recommendations
Not applicable

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, ethanol septal ablation, alcohol septal ablation

APPROVED BY GOVERNING BODIES:
The FDA does not regulate specific surgical procedures.

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

CURRENT CODING:
CPT Codes:

93583	Percutaneous transcatheter septal reduction therapy (eg, alcohol septal ablation) including temporary pacemaker insertion when performed
93799	Unlisted cardiovascular surgery

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, June 2007
Medical Policy Group, June 2009
Medical Policy Group, July 2019
Medical Policy Group, November 2020 (4): Reviewed by consensus. No change to policy statement.