

ALCOHOL SEPTAL ABLATION FOR OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY

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Overview

Hypertrophic cardiomyopathy (HCM) is a genetic disease with an autosomal pattern of inheritance characterized by hypertrophy (thickening) of the left ventricle (LV). HCM has markedly variable clinical manifestations ranging from asymptomatic to sudden cardiac death, even within a single family who share the same genetic mutation. HCM is the single most common cause of sudden cardiac death in otherwise healthy people under 35 years.

HCM may be initially suspected because of detection of a heart murmur, positive family history, new onset of symptoms such as dyspnea, or abnormal ECG pattern. It is not unusual for children younger than 13 years to carry the genetic mutation without LV hypertrophy. Substantial LV remodeling occurs with accelerated body growth during adolescence, and phenotypic expression is usually completed at physical maturity. In 25% to 70% of patients, the location and extent of cardiac hypertrophy obstructs LV outflow (the degree of obstruction is varied). In about 50% of patients, a LV outflow gradient is detectable only with exercise. LV outflow gradient detectable at rest is an independent predictor of poor prognosis in patients with HOCM. It is important to distinguish between the obstructive and nonobstructive forms of HCM based on the presence or absence of a LV outflow gradient under resting and/or provokable conditions.

The LV outflow pressure gradient contributes significantly to the development of symptoms such as dyspnea, chest pain and syncope. Pharmacologic therapies, including beta-blockers and calcium channel, are the first-line treatment for patients with symptomatic obstructive HCM. A small subset of patients with significant outflow obstruction will have severe incapacitating symptoms despite optimal pharmacologic therapy. For these patients several treatment options are available including surgery (septal myotomy-myectomy), dual chamber pacing (which has only a limited role), and alcohol septal ablation. Septal myotomy-myectomy (the Morrow Procedure) has been the gold standard treatment for severely symptomatic patients who are resistant to pharmacologic therapy for more than 40 years. During septal myotomy-myectomy, a small amount of muscle is resected from the subaortic portion of the septum. The procedure substantially reduces outflow obstruction and restores LV systolic pressure to normal by eliminating mitral valve systolic anterior motion and contact with the septum. Septal myotomy-myectomy has a low mortality rate (1 – 2 % or less) and 70% of patients report long-term substantial symptom relief and increased exercise capacity. Unfortunately, some patients are not surgical candidates because of advanced age or concomitant medical conditions. In addition, septal myotomy-myectomy is not widely available because of the surgical expertise required to perform this procedure.

In 1995, alcohol septal ablation emerged as a less invasive alternative to septal myotomy-myectomy. Symptomatic patients with left ventricular outflow obstruction have been shown to derive benefit from the intentional infarction of a portion of the interventricular septum by the infusion of 1 to 4 ml of absolute alcohol into a selectively catheterized septal artery to produce myocardial infarction. Alcohol septal ablation reduces septal thickness and motion, enlarges the LV outflow tract and decreases mitral valve systolic anterior motion mimicking the hemodynamic consequences of septal myotomy-myectomy. As with septal myotomy-myectomy, the decrease in symptoms associated with obstructive HCM is often dramatic. As a precaution, patients without permanent pacemakers usually undergo placement of a temporary pacemaker during the procedure. Patients are typically monitored for 48 to 72 hours after ablation in the coronary care unit. Post-procedure, patients are evaluated at regular intervals to assess symptoms, left ventricular outflow gradient and pharmaceutical therapy. If symptoms have not resolved and a left ventricular outflow gradient persists, options include repeating ablation or myectomy.

Alcohol septal ablation has yet to be compared with septal myotomy-myectomy in prospective randomized studies. Concerns remain with regard to the efficacy of septal ablation compared to septal myectomy in terms of acute complications, potential for arrhythmias, and long-term outcomes. Surgical septal myectomy remains the primary treatment option for most severely symptomatic, drug-refractory patients with obstructive HCM. Alcohol septal ablation is an alternative for patients at increased operative risk, without access to expert surgical centers, or who refuse surgery after both options have been discussed equitably.

Definitions

Cardiomyopathy - any disease that primarily affects the muscle of the heart.

Interventricular septum - the muscular partition between the right and left ventricles.

Pressure gradient – the change in blood pressure across a blood vessel or valve. If blood flow is decreased, there is a decrease in pressure gradient; if blood flow is increased, such as with exercise, there is an increase in pressure gradient.

Covered Services

Preauthorization is required for alcohol septal ablation for hypertrophic obstructive cardiomyopathy.

FCHP covers alcohol septal ablation for obstructive HCM when the following criteria are met:

1. Member has severe heart failure symptoms (NYHA Class III or IV¹) refractory to optimal drug therapy, such as beta-blockers, calcium channel blockers and amiodarone.

¹ NYHA Class III: Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

NYHA Class IV: Patients with cardiac disease resulting in inability to carry on 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.

2. Member has a LV outflow gradient caused by systolic anterior motion of the mitral valve (gradient \geq 50 mm Hg at rest or with provocation) measured by doppler echocardiography.
3. Member has left ventricular septal thickness \geq 15 mm in an adult or the equivalent relative to body-surface area in a child, in the absence of another cardiac or systemic disease causing ventricular hypertrophy.
4. Member does not have coexistent valve disease (mitral valve or aortic valve) or severe coronary artery disease.
5. Member does not have a need for concomitant cardiac surgical procedure such as valve replacement or bypass grafting.
6. Member fully understands the risks and limitations of this procedure including the lack of long-term survival data and risk for pacemaker dependency.

Codes

There is no specific CPT or HCPCS code for alcohol septal ablation for hypertrophic obstructive cardiomyopathy. The CPT code 93799 (unlisted cardiovascular service or procedure) should be used effective January 1, 2008. Preauthorization is required for all unlisted services and procedures, if preauthorization is not obtained, the claim will be denied with the following disposition: *Reject Not Authorized -- Vendor Liable*.

Refer to FCHP's the unlisted surgical procedures payment policy for the supporting documentation required for submitting claims using unlisted CPT codes. Diagnoses that will support the medical necessity for alcohol septal ablation must include the following in addition to the condition(s) necessitating the procedure: 425.1 hypertrophic obstructive cardiomyopathy.

Codes	Number	Description
CPT	93799	Unlisted cardiovascular service or procedure

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

Committee review dates:

Technology Assessment Subcommittee: 09/17/2008

Technology Assessment Committee: 04/09/2002, 02/21/2005, 10/14/2008

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.