

MEDICAL POLICY



SUBJECT: TRANSMYOCARDIAL REVASCULARIZATION	EFFECTIVE DATE: 11/19/99 REVISED DATE: 03/21/02, 01/16/03, 11/20/03, 09/16/04, 7/21/05, 05/18/06, 03/15/07, 02/21/08, 01/15/09 ARCHIVED DATE: 02/19/09 EDITED DATE: 02/18/10, 02/17/11, 02/16/12, 02/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, transmyocardial revascularization (TMR) has been medically proven to be effective and therefore, **medically appropriate** for patients with class III or class IV angina, who are not candidates for CABG or PTCA and meet all of the following criteria:
 - A. Presence of Class III or IV angina refractory to medical management;
 - B. Documentation of reversible ischemia;
 - C. Left ventricular ejection fraction greater than 25%;
 - D. No evidence of recent MI or unstable angina within the last 21 days; and
 - E. No severe comorbid illness, such as COPD.
- II. Based upon our criteria and assessment of the peer-reviewed literature, transmyocardial revascularization (TMR) as an adjunct to CABG has been medically proven to be effective, and therefore **medically appropriate** for patients who will be undergoing CABG but also have documented areas of ischemic myocardium that are not amenable to bypass grafting due to distal or diffuse vascular disease.
- III. Based upon our criteria and assessment of the peer-reviewed literature, *percutaneous* transmyocardial revascularization (PTMR) has not been medically proven to be effective and therefore, is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization (TMLR), is a surgical technique intended to improve blood flow to ischemic heart muscle by creating direct channels from the left ventricle into the myocardial tissue. TMR is performed using one of three different types of lasers: high energy, pulsed carbon dioxide laser; the holmium solid-state laser; or the excimer laser.

TMR has been most commonly used in patients with refractory end-stage coronary artery disease (CAD). More specifically, these are patients with stable class III or class IV angina, who have failed maximal medical management, have hypoperfused but viable myocardium, and who are not candidates for coronary artery bypass graft (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA). Additional studies support the use of TMR as an adjunct to CABG surgery in patients with end stage CAD who can be partially revascularized with CABG but have other areas of ischemia that cannot be treated with bypass grafting due to diffuse or distal vascular disease. Few modifications to CABG surgery need to occur to accommodate the addition of TMR.

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Transmyocardial revascularization is traditionally performed via thoracotomy; more recently, less invasive approaches are being studied. Various port access procedures are being evaluated to use TMR using novel robotic and thoracoscopic techniques.

Transmyocardial revascularization can also be performed by the percutaneous route (PTMR). PTMR (now being called percutaneous myocardial channeling or PMC) is a catheter-based approach using Ho:YAG laser revascularization under fluoroscopic guidance. The main differences between PTMR and TMR are the obvious non-surgical approach used by PTMR, and the differences in the wavelengths of the laser lights used. In contrast to TMR, which creates transmural channels from the epicardial surface, PTMR devices operate from the endocardial surface and are designed to penetrate less than the full wall thickness.

RATIONALE:

There are several FDA approved Ho:YAG and CO₂ lasers for TMR as an alternative to CABG; they include the Heart Laser™, Heart Laser 2™ and the Eclipse TMR 2000™. There are no FDA approved lasers for TMR used with CABG surgery. The use of these lasers as an adjunct to CABG surgery is an off label use.

Catheter-based PTMR systems have been developed; all of which are based on the Ho:YAG laser. None have obtained FDA approval. Although less invasive than TMR, there are potential disadvantages to the PTMR approach. To minimize the possibility of cardiac tamponade, the myocardial channels created by PTMR are not as deep as those made by TMR. Also, positioning the laser under fluoroscopic guidance is less precise than the direct visual control of TMR.

The mechanism of why TMR is successful remains unclear. There are several theories for its success: the sinusoidal channel theory; nonspecific histologic response to injury (angiogenesis); denervation of ischemic myocardium; or a placebo effect. It may be a combination of more than one of these theories that is actually responsible for the improvement in symptom following TMR. There is some concern surrounding the mechanism of how TMR actually works; studies often show improvement in symptoms such as exercise tolerance and angina severity/frequency, yet cardiac perfusion and flow studies most often do not show significant improvement.

In 2004, the Society of Thoracic Surgeons published recommendations regarding TMR; the recommendations do not distinguish between open and percutaneous approaches (Bridges, 2004). Class I recommendations were defined as conditions for which there is evidence or general agreement that a given procedure or treatment is useful and effective.

- I. There was 1 Class I recommendation for TMR as solo therapy: “Patients with an ejection fraction greater than 0.30 and CCS class III or IV angina that is refractory to maximal medical therapy. These patients should have reversible ischemia of the left ventricular free wall and coronary artery disease corresponding to the regions of myocardial ischemia. In all regions of the myocardium, the coronary disease must not be amenable to CABG or percutaneous transluminal angioplasty either as a result of (1) severe diffuse disease, (2) lack of suitable targets for complete revascularization, or (3) lack of suitable conduits for complete revascularization.” This recommendation was based on data derived from multiple randomized clinical trials.
- II. There were no Class I recommendations for TMR combined with CABG. There was one Class IIa recommendation, defined as conditions for which there is conflicting evidence or a divergence of opinion, but where the weight of evidence or opinion is in favor of usefulness or efficacy. The Class IIa recommendation is: “Patients with angina (Class I-IV) in whom CABG is the standard of care who also have at least one accessible and viable ischemic region with demonstrable coronary artery disease that cannot be bypassed either because of (1) severe diffuse disease, (2) lack of suitable targets for complete revascularization, or (3) lack of suitable conduits for complete revascularization.” This recommendation was based on data derived from a single randomized trial (Allen, 2004) and data from a Society of Thoracic Surgeons National Cardiac Database.

A meta-analysis (Liao, 2005) of seven randomized trials involving 1,053 patients concluded at 1-year follow-up that TMR produced a significant improvement in angina class but no improvement in survival. Publications are beginning to

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describe experience and intermediate-term outcomes for less-invasive approaches to TMR. For example, Allen (2005) reported results for 10 patients who underwent TMR using a completely thoracoscopic, closed-chest approach. In this small series with an average 8-month follow-up, there were no major complications and anginal symptoms improved.

There is insufficient published medical evidence to demonstrate the safety, efficacy, and long-term outcomes of percutaneous myocardial revascularization (PMR) for the treatment of refractory angina. A clinical trial protocol for this approach was announced in early 2006.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	33140	Transmyocardial laser revascularization, by thoracotomy
	33141	Transmyocardial laser revascularization, by thoracotomy; performed at the time of other open cardiac procedure(s)

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HCPCS: No codes

411.1 Intermediate coronary syndrome (including unstable angina)

<u>ICD10:</u>	I20.0-I20.9	Angina pectoris (code range)
	I25.10-I25.19	Atherosclerotic heart disease of native coronary artery (code range)
	I25.5	Ischemic cardiomyopathy
	I25.6	Silent myocardial ischemia
	I25.700-I25.709	Atherosclerosis of coronary artery bypass graft(s)(code range)
	I25.710-I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) (code range)
	I25.720-I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) (code range)
	I25.730-I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) (code range)
	I25.750-I25.759	Atherosclerosis of native coronary artery of transplanted heart (code range)
	I25.760-I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart (code range)
	I25.790-I25.799	Atherosclerosis of other coronary artery bypass graft(s) (code range)
	I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
	I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
	I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
	I25.89	Other forms of chronic ischemic heart disease

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* Key article

KEY WORDS:

TMR, PTMR, Percutaneous Transmyocardial revascularization.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Transmyocardial Revascularization. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=120&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAAA%3d%3d&>.