

## Evidence Based Guideline

### Transmyocardial Revascularization

**File Name:** transmyocardial\_revascularization  
**Origination:** 6/1997  
**Last CAP Review:** 6/2011  
**Next CAP Review:** 6/2012  
**Last Review:** 6/2011

#### Description of Procedure or Service

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Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization (TMLR), is a surgical technique that attempts to improve blood flow to ischemic heart muscle via the creation of direct channels from the left ventricle into the myocardium. TMR is performed via a thoracotomy, with the patient under general anesthesia. Cardiopulmonary bypass is not required. A laser probe is placed on the surface of the myocardium, and while the heart is in diastole, the laser is discharged to create a channel through the myocardium into the left ventricle. Less invasive approaches to TMR are also 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 (also called percutaneous myocardial channeling or PMC) is a catheter-based system using Ho:YAG laser revascularization under fluoroscopic guidance. It is performed in Europe, but is not currently approved by the U.S. Food and Drug Administration (FDA). PTMR is performed by interventional cardiologists, who create myocardial channels with lasers positioned at the endocardial surface inside the left ventricle. Although less invasive than TMR, there are potential disadvantages to the PTMR approach. To minimize the possibility of cardiac tamponade, a potentially fatal condition in which the pericardium fills with blood, 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. Less invasive, e.g., robotic techniques for use of this procedure are also being studied.

Open TMR has been investigated in 2 populations of patients: 1) patients with ischemic myocardium who are not candidates for other types of revascularization procedures, such as coronary artery bypass surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA) due to anatomical features of their coronary circulation; and 2) as an adjunct to coronary artery bypass grafting in patients with areas of ischemic myocardium that are not amenable to surgical revascularization. Other potential applications of TMR include its use as an adjunct to stem-cell based therapy.

The Heart Laser™ received final FDA approval to market in 1998 for the treatment of patients with stable class III or IV angina refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis not amendable to direct coronary revascularization. The Eclipse TMR 2000™ received FDA approval for similar indications in July 1999. Neither device is approved for use as an adjunct to CABG. Use of either device for this purpose would be considered an off-label indication.

**\*\*\*Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Evidence Based Guideline for Transmyocardial Revascularization

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Open transmyocardial laser revascularization is recommended for patients with class III or IV angina,

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who are not candidates for coronary artery bypass graft (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA) surgery who meet ALL of the following criteria:

- Presence of class III or IV angina refractory to medical management
- Documentation of reversible ischemia
- Left ventricular ejection fraction >30%
- No evidence of recent MI or unstable angina within the last 21 days
- No severe comorbid illness such as chronic obstructive pulmonary disease (COPD)

Open transmyocardial laser revascularization may be recommended as an adjunct to coronary artery bypass grafting (CABG) in those patients with documented areas of ischemic myocardium that are not amenable to surgical revascularization.

### **Medical Evidence regarding Transmyocardial Revascularization indicates it is not recommended in the following situations**

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Transmyocardial revascularization is not recommended for any use other than those listed above.

Percutaneous transmyocardial laser revascularization is not recommended.

### **Benefits Application**

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This guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this guideline.

### **Billing/Coding/Physician Documentation Information**

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This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 33140, 33141*

### **Scientific Background and Reference Sources**

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National Association TEC evaluation 12/96

Horvath KA, Cohn LH. Transmyocardial Laser Revascularization: results of a multicenter trial with transmyocardial laser revascularization used as sole therapy for end-stage coronary artery disease. *The Journal of Thoracic and Cardiovascular Surgery*. 1997;113(4):645-654.

Frazier OH, Kadipasaoglu, K. Transmyocardial Laser Revascularization. *Texas Heart Institute Journal*. 1998;25(1):24-29

BCBSA TEC Assessment. January 1999, pg. 20-24

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Transmyocardial Revascularization (TMR) for Treatment of Severe Angina.  
www.hcfa.gov/pubforms/transmit/ab992260.htm. 4/21/1999

Medical Policy Advisory Group - 8/12/99

Medical Policy Reference Manual 11/1/1999

Specialty Matched Consultant Advisory Panel. 11/199

Medical Policy Advisory Group 12/2/1999

BCBSA Medical Policy Reference Manual - 5/31/01; 7.01.54

Specialty Matched Consultant Advisory Panels - 12/2001

Specialty Matched Consultant Advisory Panel - 11/2003

Specialty Matched Consultant Advisory Panel - 11/2005

U.S. Food and Drug Administration 501(k) Summary for The Heart Laser CO2 TMR System retrieved on 8/20/1998 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/P950015a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/P950015a.pdf)

U.S. Food and Drug Administration 501 (k) Summary for The Eclipse TMR Holmium Laser System retrieved on 2/11/1999 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/P970029a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/P970029a.pdf)

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.54, 1/14/2010

Specialty Matched Consultant Advisory Panel 6/2010

Specialty Matched Consultant Advisory Panel review 6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.54, 8/11/11

## Policy Implementation/Update Information

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6/97 Original policy issued.

5/99 Revised based on BCBSA TEC Assessment, HCFA guidelines, and several journal articles indicating that there are health outcome advances with the surgery.

7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.

8/99 Medical Policy Advisory Group

12/99 Reaffirmed, Medical Policy Advisory Group

12/00 2001 CPT code added; 33141. System coding changes.

12/01 Revised. Indication removed from non-covered section that states "performed as a percutaneous procedure". Removed indication from non-covered section and added to covered section that states, "as an adjunct to coronary artery bypass surgery (CABG) in patients with documented large areas of remaining ischemic myocardium that are not amenable to surgical revascularization". Added New York Heart Association (NYHA) Functional Classification table for clarity.

11/03 Biannual policy review. Specialty Matched Consultant Advisory Panel review. Reaffirm policy.

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Format change for consistency. No criteria change to policy.

11/17/05 Biennial policy review. Specialty Matched Consultant Advisory Panel review 11/07/05. Policy reflected current standard of care. Policy status changed to "Active policy, no longer scheduled for routine literature review."

9/18/06 Medical Policy changed to Evidence Based Guideline. (adn)

8/3/2010 Status changed to active Evidence Based Guideline and will undergo routine literature review. Guideline Policy number removed. References updated. Specialty Matched Consultant Advisory Panel review 6/2010.(mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. Replaced the phrase "medically necessary" with "recommended" and replaced the word "investigational" with "not recommended." (mco)

9/30/11 References updated. No changes to Guideline Statement. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.