# MEDICAL POLICY

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| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
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| POLICY NUMBER | MP- 1.057 |

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| Original Issue Date (Created): | February 25, 2003 |
| Most Recent Review Date (Revised): | September 24, 2013 |
| Effective Date: | November 1, 2013 |

## I. POLICY

Open transmyocardial laser revascularization may be considered **medically necessary** for patients with class III or IV angina, **who are not candidates** for coronary 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 and failed maximum medical management;
- Documentation of reversible ischemia;
- Left ventricular ejection fraction > 30%;
- No evidence of recent myocardial infarction or unstable angina within the last 21 days; and
- No severe comorbid illness such as chronic obstructive pulmonary disease.

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

Percutaneous transmyocardial laser revascularization is **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

## II. PRODUCT VARIATIONS

*[N] = No product variation, policy applies as stated*
*[Y] = Standard product coverage varies from application of this policy, see below*

[N] Capital Cares 4 Kids

[N] PPO

[N] HMO

[Y] SeniorBlue HMO*

[Y] SeniorBlue PPO*

[N] Indemnity

[N] SpecialCare

[N] POS

[N] FEP PPO

* Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 20.6, Transmyocardial Revascularization, for additional coverage indications.

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|---|---|
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## III. DESCRIPTION/BACKGROUND

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 under general anesthesia via a thoracotomy. 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 apprpoaches 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 now being 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 two populations: 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 as an adjunct to coronary artery bypass grafting in patients with areas of ischemic myocardium that is not amendable 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 uses as an adjunct to CABG. Use of either device for this purpose would be considered an off-label indication.

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|---|---|
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## IV. RATIONALE

This policy is regularly updated with.the most recent literature search performed for the period of June 2012 through June 2013. Following is a summary of the key literature to date:

**Open Transmyocardial Laser Revascularization**

This portion of the policy is based in part on 2 TEC Assessments, a 1998 Assessment (1) that focused on the use of open transmyocardial laser revascularization (TMR) as an alternative to inoperable coronary artery disease and a 2001 Assessment (2) that focused on its use as an adjunct to coronary artery bypass surgery (CABG).

*Open TMR in Patients with Inoperable Coronary Artery Disease*

The 1998 TEC Assessment offered the following observations and conclusions (1):

- Results of randomized controlled clinical trials suggested that patients with refractory, nonoperable class III or IV angina respond well to TMR. Specifically, results of 1 trial reported that 86% of those assigned TMR were in angina class I or II at 12 months of follow-up compared with 30% in the medical management group. In addition, a decline in the number of hospital admissions favored TMR. The data on morbidity and mortality were inconclusive but were in favor of an equivalent or lower mortality rate with TMR.

Patients enrolled in these trials were carefully selected to maximize the benefit of TMR. All patients had class III or IV angina that was refractory to medical management and objective evidence of reversible ischemia on exercise testing or perfusion scanning. In addition, a variety of exclusion criteria were used to minimize the risk of open thoracotomy. These exclusion criteria varied slightly among the trials and have evolved in response to recognition of high-risk subgroups among the initial randomized controlled trials (RCTs). In general, in patients with recent unstable angina or myocardial infarction (MI), an ejection fraction of less than 30%, and severe comorbid illness were excluded from these trials.

The 3 unpublished RCTs cited in the original TEC Assessment (1) have since appeared in the literature. (3-5) Since then, 3 additional RCTs with similar design have been published. Schofield and colleagues (6) randomized 188 patients with refractory angina to TMR via a high-energy CO2 laser or medical management alone. At 12 months, 25% of the patients assigned to TMR improved by at least 2 Canadian Cardiovascular Society (CCS) anginal classes, compared to only 4% in the medical management group ($p<0.001$). There were no statistically significant differences in exercise duration, 12- minute walk distance, or radionucleotide perfusion. The number of patients improving by 2 or more angina classes was much less than in the 3 previously cited RCTs. There was 5% perioperative mortalityfor

the TMR group and a lower overall survival at 12 months (89% vs. 96%, p=0.14), but this difference did not reach statistical significance.

Aaberge and others (7) compared 50 patients randomized to pulsed CO2 laser TMR with 50 patients randomized to medical management. At 12 months, 39% of the patients assigned to TMR improved by at least 2 New York Heart Association (NYHA) anginal classes versus 0% in the medical management group (both the NYHA and CCS contain 4 anginal classes, but class 1 in the NYHA system allows no symptoms, potentially making a 2-class improvement more difficult to achieve). Exercise capacity was not improved by TMR. There was a 4% perioperative mortality rate with lower overall survival at 12 months (88% vs. 92%, respectively, p=NS), but this difference did not reach statistical significance.

Jones et al. (8) randomized 86 patients with refractory angina to TMR with a Ho:YAG laser or to medical management. At 12 months, the TMR group had an average improvement of slightly more than 2 CCS anginal classes over the medical management group. The TMR group also had a significant improvement in exercise duration (490 vs. 294 seconds, respectively, p=0.0002). There was only 1 perioperative death in the TMR group, but overall survival data were not provided.

An analysis of registry data evaluated outcomes of TMR in 661 patients who underwent TMR alone for refractory angina. (9, 10) This study reported that many patients undergoing TMR in clinical practice differed from those in the randomized trials, especially in regard to the presence of high-risk factors such as unstable angina or recent MI. Patients with unstable angina undergoing TMR had a 30-day mortality that was almost double that of patients without unstable angina (8.3% vs. 4.3%, respectively, $p<0.05$), while patients with an MI in the last 21 days had a mortality risk that was more than double that of patients without recent MI (13.0% vs. 5.4%, respectively, $p<0.05$). Finally, Allen et al. reported on the 5-year results of his earlier trial, (3) which demonstrated at 5 years that the significant anginal relief observed 12 months after sole therapy TMR was sustained long-term and continued to be superior to that observed for patients maintained on continued medical management alone. (11)

These additional studies support the conclusions of the TEC Assessment that TMR improves anginal symptoms in patients with refractory angina, compared to medical management, and confirm the need for careful selection of patients undergoing the procedure. These studies differ from the original 3 trials in that fewer patients improved by at least 2 anginal classes, suggesting that the magnitude of benefit may be less than in the first 3 trials. These trials do not provide conclusive evidence on whether TMR improves survival or exercise capacity. The data also reinforce that achieving beneficial outcomes of TMR depends on careful patient selection as follows:

- Patients with 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 TMR as an Adjunct to CABG*

The 2001 TEC assessment offered the following observations and conclusions (2):

- The TEC Assessment focused on 2 randomized single-blind trials that compared outcomes of patients who underwent CABG alone versus CABG plus TMR. While the smaller of the 2 trials, enrolling only 42 patients, showed a trend toward an improved perioperative mortality associated with TMR, this outcome reached statistical significance in the second larger trial, enrolling 266 patients. In this trial, perioperative mortality decreased from 7.5% in the control group to 1.5% in the TMR group.
- The scientific basis of the improvement in perioperative mortality is unknown, yet the randomized trial was well-designed and conducted at multiple institutions, which supported the conclusions.
- There was no significant improvement in subjective symptoms and exercise tolerance, which were the inverse of prior findings evaluating TMR as sole therapy (see above).

A 2005 meta-analysis of 7 randomized trials, by Liao and colleagues, involving 1,053 patients concluded, at 1-year follow-up, that TMR produced a significant improvement in angina class but no improvement in survival. (12) In 2008, Campbell et al., conducted a systematic review of TMR and percutaneous TMR (PTMR) for refractory angina pectoris. (13) The authors evaluated 16 RCTs (10 TMR, 6 PTMR) and 13 non-randomized studies (8 TMR, 5 PTMR) and concluded TMR and PTMR were not effective in treating refractory angina and did not improve objective measures of myocardial function (i.e., myocardial perfusion tests and left ventricular ejection fraction) and 12-month survival. While subjective, patient reported outcomes showed some improvement with TMR and PTMR, the review noted improvements in angina symptoms and exercise tolerance were lost or reduced when blinding of treatment occurred. The review found the mortality risks and risk of adverse events raised safety concerns. Additionally, the review also noted most studies were conducted in the United States on male patients, and therefore, there is a lack of evidence on outcomes in wider populations. A 2009 Cochrane review of 7 studies of TMR noted that while improvement in angina was greater in treated patients than in control patients, 1- year mortality was similar between the groups, but 30-day mortality was greater in the TMR group. (14) These authors concluded that there was insufficient evidence to determine whether the clinical benefits of TMR outweighed the potential risks

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**Percutaneous Transmyocardial Revascularization (PTMR)**

Although PTMR was designed as a less-invasive alternative to TMR, no studies have directly compared the 2 procedures. The various differences between PTMR and TMR outlined here require that they be considered as distinct entities.

At the time of the original TEC Assessment, (1) no outcome data on PTMR were available, although early observational data suggested that the symptomatic benefit of PTMR approached that seen with TMR. (9) As noted above, in a 2008 systematic review, Campbell et al., concluded PTMR was not an effective treatment for refractory angina pectoris. (13) A 2010 meta-analysis by McGillion and colleagues evaluated 7 RCTs to compare PTMR to maximally tolerated antianginal therapy management. (15) Atotal of 1,213 patients with CCS class III-IV refractory angina on optimal medical management were included in the trials analyzed. Exclusion criteria for the trials included recent myocardial infarction (MI), aortic stenosis, mechanical aortic valve, peripheral vascular disease precluding catheter insertion, left ventricular ejection fraction less than 25-30%, and myocardial wall thickness in laser-targeted areas of less than 8-9 mm. All patients randomized to PTMR groups in the trials received low-dose holmium:YAG lasers except for one arm of one trial, which used a high-dose holmium:YAG laser. The high-dose laser arm was excluded from the primary analysis. Maximally-tolerated antianginal therapy was not changed in any treatment group across the trials.

Data on 12-month outcomes from 5 of the trials examined were analyzed and demonstrated that PTMR significantly reduced angina symptoms by at least 2 CCS classes with a pooled odds ratio (OR) of 2.13 (95% confidence interval [CI]: 1.22 to 3.73) (n=3 studies). PTMR also significantly improved self-reported, health-related quality of life, using the Seattle Angina Questionnaire, in the areas of angina frequency, standardized mean differences (SMD) were 0.29 (95% CI: 0.05 to 0.52), disease perception SMD was 0.37 (95% CI: 0.14 to 0.61), and physical limitations SMD was 0.29 (95% CI: 0.05 to 0.53) (n=2 studies). Significant differences were not found in patient-reported angina stability or treatment satisfaction. Nor were significant differences found in exercise duration or all-cause mortality. Additionally, when a secondary analysis including the high-dose laser group from Leon et al, was performed, the differences in angina class, exercise duration, and health-related quality of life (HRQL) were no longer significant between treatment and control groups.

This meta-analysis suggests that PTMR may have benefits similar to open TMR, but the conclusions are limited by several factors. Although 7 studies were included in the review, the results for each individual outcome were based on only 2 or 3 studies. The findings of outcome benefits on combined analysis were not robust, as the addition of a third treatment arm from one trial eliminated the significant findings. Sensitivity analysis was not performed by study quality, presence of blinding, or the presence of a sham placebo, factors which may have been able to determine whether group differences reported in some of the trials were

due to a treatment effect versus a placebo/nonspecific effect. The authors identified a need for further studies to evaluate adverse events, disease-specific mortality, laser dosages, and the underlying mechanisms of PTMR.

The following is an example of 2 published RCTs included in the McGillion et al. meta-analysis above, that compared PTMR to medical management. In the PACIFIC trial, (16) Oesterle et al. compared PTMR (n=110) with medical management (n=111) in patients with refractory angina. Several patients in both the PTMR group (n=10) and the medical management group (n=14) received percutaneous transluminal coronary angioplasty (PTCA), CABG, or TMR within the 12-month follow-up period. When these patients were included in an analysis at 12 months, 46% in the PTMR group improved by at least 2 CCS anginal classes, compared to 11% in the medical management group. However, a subsequent masked assessment of anginal scores revealed that 28% of the improvement was attributable to investigator bias. When the patients who received an additional procedure were excluded, there was still an 82.5-second improvement in exercise duration in the PTMR group over the medical management group. There weremore deaths at 12 months in the PTMR group, but the difference was not statistically significant (8 vs. 3, p=0.21).

In the second published RCT, (17) Stone and coworkers studied 141 patients with refractory angina and 1 or more chronic total occlusions (CTOs) in territories with reversible ischemia. This study group was derived from a larger group of patients in whom PTCA of a CTO was attempted. If PTCA was not possible, the patients were immediately randomized to PTMR (n=71) or a sham PTMR procedure followed by medical management (n=70). At 6 months, 49% of the patients assigned to PTMR improved by at least 2 CCS classes versus 37% in the sham group. This difference was not statistically significant (p=0.33). There was a small increase in exercise duration (64 vs. 52 seconds) in the PTMR group over the sham group that was also not statistically significant (p=0.73). There was no difference in mortality at 6 months (8.6% vs. 8.8%, p=NS). The authors concluded that the similar degree of benefit in the sham group compared to the PTMR group suggests that improvement from PTMR may be largely due to a placebo effect.

**Ongoing Clinical Trials**

A search of online site ClinicalTrials.gov in July 2013 found 3 small cohort trials on TMR: with bone marrow aspirate concentrate (NCT01285297); with bone marrow stromal stem cells (NCT01557543) and with cardiac magnetic resonance imaging (MRI) evaluation (NCT01287910). A registry study on TMR is also ongoing (NCT01827319). No PTMR trials were identified

**Summary**

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 may be performed via a thoracotomy or percutaneously.

Several RCTs have demonstrated that TMR may provide significant improvements in angina symptoms compared to optimal medical management. While studies have not shown improvements in survival or significant increases in exercise duration, TMR may be considered medically necessary for patients with class III or IV angina, who are not candidates for coronary artery bypass graft (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA) surgery, based on improvement in symptoms. Candidates for TMR must also be refractory to medical management, have reversible ischemia, and left ventricular ejection fraction greater than 30%. TMR may also be considered medically necessary as an adjunct to CABG in those patients with documented areas of ischemic myocardium that are not amenable to surgical revascularization.

While PTMR is less invasive than TMR and some studies have shown improvements in angina symptoms and health-related quality of life, the available evidence is less consistent in showing whether PTMR improves net health outcomes. Additionally, there is no U.S. Food and Drug Administration (FDA) approved PTMR device available. Therefore, PTMR is considered investigational. Studies on PTMR with longer follow-up and further data on safety, adverse events, and survival are needed.

**Practice Guidelines and Position Statements**

In 2012, guidelines for stable ischemic heart disease were developed through a collaborative effort of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. (18) These guidelines indicate TMR may be considered as an alternative therapy for refractory angina in patients with stable ischemic heart disease (Class IIb, Level of evidence B: benefit greater than risk, evidence less well-established).
The American College of Cardiology/American Heart Association (ACC/AHA) published guidelines for coronary artery bypass graft surgery (19) and percutaneous artery intervention (20). The most recent 2011 versions of these guidelines both indicate that TMR may be performed as an adjunct to CABG on viable ischemic myocardium that is perfused by arteries that are not amenable to grafting (Class IIb, Level of evidence B: benefit greater than risk, evidence less well-established).

In 2004 (reaffirmed in 2009), the Society of Thoracic Surgeons published recommendations regarding open TMR; the recommendations do not discuss the percutaneous approach

although it is noted to be less promising than open TMR. (21) 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. There was one class I recommendation for TMR as solo therapy as follows:
"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 amendable 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. There were no class I recommendations for TMR combined with CABG. There was one class IIa recommendation, which defined conditions for which there is conflicting evidence or a divergence of opinion but for which the weight of evidence or opinion is in favor of usefulness or efficacy. The class IIa recommendation is as follows:

"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 (22) and data from a Society of Thoracic Surgeons National Cardiac Database. (9) These two class I and class IIa recommendations are essentially consistent with the indications considered medically necessary in this policy for open TMR.

In 2009, the National Institute for Health and Clinical Excellence (NICE) issued guidance on TMR (23) and PTMR (24) based on a 2008 systematic review by Campbell et al, noted above. (13) The NICE guidance on TMR states, "Current evidence on transmyocardial laser revascularization for refractory angina pectoris shows no efficacy, based on objective measurements of myocardial function and survival. Current evidence on safety suggests that the procedure may pose unacceptable risk. Therefore, this procedure should not be used."
The 2009 NICE guidance for PTMR states, "Current evidence on percutaneous laser revascularization for refractory angina pectoris shows no efficacy and suggests that the procedure may pose unacceptable safety risks. Therefore, this procedure should not be used."

| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
|---|---|
| POLICY NUMBER | MP- 1.057 |

## V. DEFINITIONS

**CLASS III ANGINA** refers to marked limitation of ordinary physical activity. Angina occurs on walking one to two blocks and climbing one flight of stairs in normal conditions at a normal pace.

**CLASS IV ANGINA** refers to inability to carry on physical activity without discomfort - angina symptoms may be present at rest.

**CORONARY ARTERY BYPASS SURGERY (CABG)** is the surgical establishment of a shunt that permits blood to travel from the aorta or internal mammary artery to a branch of the coronary artery at a point past an obstruction.

**ISCHEMIA** refers to a temporary deficiency of blood flow to an organ or tissue.

**OFF- LABEL** refers to the use of a drug for a disease or condition other than the indication for which it was approved by the FDA.

**PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)** is a method of treating localized coronary artery narrowing. A special double-lumen catheter is designed so that a cylindrical balloon surrounds a portion of it. After the catheter is inserted into the artery, inflation of the balloon dilates the narrowed vessel.

**REVASCULARIZATION** is the restoration of blood flow to a part.

**THORACOTOMY** refers to surgical incision of the chest wall.

## VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

## VII. DISCLAIMER

*Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
|---|---|
| POLICY NUMBER | MP- 1.057 |

## VIII. REFERENCES

1. *Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Transmyocardial revascularization for the treatment of coronary artery disease. TEC Assessments 1998; Volune 13, Tab 23.*

2. *Blue Cross Blue Shield Association Technology Evaluation Center (TEC). TMR as an adjunct to CABG surgery for the treatment of coronary artery disease. TEC Assessments 2001; Volume 16, Tab 1.*

3. *Frazier OH, March RJ, Horvath KA. Transmyocardial revascularization with a carbon dioxide laser in patients with end-stage coronary artery disease. N Engl J Med 1999; 341(14):1021-8*

4. *Allen KB, Dowling RD, Fudge TL et al. Comparison of transmyocardial revascularization with medical therapy in patients with refractory angina. N Engl J Med 1999; 341(14):1029-36.*

5. *Burkhoff D, Schmidt S, Schulman SP et al. Transmyocardial laser revascularisation compared with continued medical therapy for treatment of refractory angina pectoris: a prospective randomised trial. ATLANTIC Investigators. Angina Treatments-Lasers and Normal Therapies in Comparison. Lancet 1999; 354(9182):885-90.*

6. *Schofield PM, Sharples LD, Caine N et al. Transmyocardial laser revascularisation in patients with refractory angina: a randomised controlled trial. Lancet 1999; 353(9152):519-24.*

7. *Aaberge L, Nordstrand K, Dragsund M et al. Transmyocardial revascularization with CO2 laser in patients with refractory angina pectoris. Clinical results from the Norwegian randomized trial. J Am Coll Cardiol 2000; 35(5):1170-7.*

8. *Jones JW, Schmidt SE, Richman BW et al. Holmium:YAG laser transmyocardial revascularization relieves angina and improves functional status. Ann Thorac Surg 1999; 67(6):1596-601; discussion 601-2.*

9. *Peterson ED, Kaul P, Kaczmarek RG et al. From controlled trials to clinical practice: monitoring transmyocardial revascularization use and outcomes. J Am Coll Cardiol 2003; 42(9):1611-6.*

10. *Saririan M, Eisenberg MJ. Myocardial laser revascularization for the treatment of end-stage coronary artery disease. J Am Coll Cardiol 2003; 41(2):173-83.*

*11. Allen KB, Dowling RD, Angell WW et al. Transmyocardial revascularization: 5-year follow-up of a prospective, randomized multicenter trial. Ann Thorac Surg 2004; 77(4):1228-34.*

*12. Liao L, Sarria-Santamera A, Matchar DB et al. Meta-analysis of survival and relief of angina pectoris after transmyocardial revascularization. Am J Cardiol 2005; 95(10):1243-5.*

13. *Campbell F Messina J, FitzGerald P et al. Systematic review of the efficacy and safety of transmyocardial and percutaneous laser revascularisation for refractory angina pectoris. November 2008. Available online at: http://www.nice.org.uk/IP374review. Last accessed July 2013.*

*14. Briones E, Lacalle JR, Marin I. Transmyocardial laser revascularization versus medical therapy for refractory angina. Cochrane Database Syst Rev 2009; (1):CD003712.*

*15. McGillion M, Cook A, Victor JC et al. Effectiveness of percutaneous laser rOesterle SN, Sanborn TA, Ali N et al. Percutaneous transmyocardial laser revascularisation for severe angina: the PACIFIC randomised trial. Potential Class Improvement From Intramyocardial Channels. Lancet 2000; 356(9243):1705-10.*

*17. Stone GW, Teirstein PS, Rubenstein R et al. A prospective, multicenter, randomized trial of percutaneous transmyocardial laser revascularization in patients with nonrecanalizable chronic total occlusions. J Am Coll Cardiol 2002; 39(10):1581-7.*

*18. Fihn SD, Gardin JM, Abrams J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012; 60(24):e44-e164.*

*19. Hillis LD, Smith PK, Anderson JL et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Developed in collaboration with the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. J Am Coll Cardiol 2011; 58(24):e123-210.*

*20. Levine GN, Bates ER, Blankenship JC et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the*

*Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol 2011; 58(24):e44-122.*

*21. Bridges CR, Horvath KA, Nugent WC et al. The Society of Thoracic Surgeons practice guideline series: transmyocardial laser revascularization. Ann Thorac Surg 2004; 77(4):1494-502.*

*22. Allen KB, Dowling RD, DelRossi AJ et al. Transmyocardial laser revascularization combined with coronary artery bypass grafting: a multicenter, blinded, prospective, randomized, controlled trial. J Thorac Cardiovasc Surg 2000; 119(3):540-9.*

*23. National Institute for Health and Clinical Excellence. Transmyocardial laser revascularisation for refractory angina pectoris. Interventional procedure guidance 301. May 2009. Available online at: http://publications.nice.org.uk/transmyocardial-laser-revascularisation-for-refractory-angina-pectoris-ipg301. Last accessed July 2013.*

*24. National Institute for Health and Clinical Excellence. Percutaneous laser revascularisation for refractory angina pectoris. Interventional procedure guidance 302. May 2009. [Website]: http://publications.nice.org.uk/percutaneous-laser-revascularisation-for-refractory-angina-pectoris-ipg302.Available online evascularization therapy for refractory angina. Vasc Health Risk Manag 2010; 6:735-47.*

*25. Centers for Medicare and Medicaid Services. National Coverage Determination for Transmyocardial Revascularization (20.6). July 1, 1999; (100-3).*

*26. Taber's Cyclopedic Medical Dictionary, 19th edition.*

| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
|---|---|
| POLICY NUMBER | MP- 1.057 |

## IX. CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

### Covered when medically necessary:

| CPT Codes ® | | | | | | | |
|---|---|---|---|---|---|---|---|
| 33140 | 33141 | 33999 | | | | | |



| ICD-9-CM Diagnosis Code* | Description |
|---|---|
| 411.1 | Intermediate coronary syndrome (including unstable angina) |
| 413.0-413.9 | Angina pectoris code range |
| 414.00-414.07 | Coronary atherosclerosis code range |
| 414.8-414.9 | Chronic ischemic heart disease code range |

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

### The following ICD-10 diagnosis codes will be effective October 1, 2014:

| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
|---|---|
| POLICY NUMBER | MP- 1.057 |

| ICD-10-CM Diagnosis Code* | Description |
|---|---|
| I20.0-I20.9 | Intermediate coronary syndrome code range |
| I25.10-125.119 | Angina pectoris code range |
| I25.89 | Other forms of chronic ischemic heart disease |
| 125.9 | Chronic ischemic heart disease |

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

## X. POLICY HISTORY

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| MP 1.057 | CAC 10/28/02 |
| | CAC 4/27/04 |
| | CAC 6/28/05 |
| | CAC 7/25/06 |
| | CAC 7/31/07 |
| | CAC 7/29/08 |
| | CAC 7/28/09 Consensus Review |
| | CAC 4/26/11 Adopt BCBSA. No changes to policy statements. |
| | CAC 6/26/12 Consensus, no change to policy statements, references updated. |
| | 7/29/13 Admin coding review complete--rsb |
| | CAC 9/24/13 Consensus. No change to policy statements, references updated. Rationale section added. |



**[Note: Final page is signature page and is kept on file, but not issued with Policy.]**

| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
|---|---|
| POLICY NUMBER | MP- 1.057 |




**[Note: Final page is signature page and is kept on file, but not issued with Policy.]**