7.01.54	Transmyocardial Revascularization		
Original Policy Date:	March 30, 2015	**Effective Date:**	May 1, 2024
Section:	7.0 Surgery	**Page:**	Page 1 of 14

Policy Statement

I. Transmyocardial laser revascularization may be considered **medically necessary** for individuals with class III or IV angina, who are not candidates for coronary artery bypass graft surgery or percutaneous transluminal coronary angioplasty surgery, who 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 30%
   D. No evidence of recent myocardial infarction or unstable angina within the last 21 days
   E. No severe comorbid illness such as chronic obstructive pulmonary disease

II. Transmyocardial laser revascularization may be considered **medically necessary** as an adjunct to coronary artery bypass graft in those individuals with documented areas of ischemic myocardium that are not amenable to surgical revascularization.

III. Transmyocardial laser revascularization is considered **investigational** for all other indications not meeting the above criteria.

IV. Percutaneous transmyocardial laser revascularization is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization, is a surgical technique that attempts to improve blood flow to ischemic heart muscles by creating direct channels from the left ventricle into the myocardium. TMR may be performed via a thoracotomy or percutaneous TMR (PTMR).

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these

instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 1998, the Heart Laser™ was approved by the FDA through the premarket approval process 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 amenable to direct coronary revascularization. In 1999, the Eclipse TMR 2000™ was approved by the FDA through the premarket approval process for similar indications. Neither device is approved for use as an adjunct to coronary artery bypass surgery. Use of either device for this purpose would be considered an off-label indication. FDA product code: MNO.

Rationale

Background

Coronary Ischemia

Two populations of patients are candidates for transmyocardial revascularization (TMR): (1) those with ischemic heart disease and angina pectoris and (2) those undergoing percutaneous coronary intervention or coronary artery bypass surgery who do not achieve complete revascularization.[1,]

Transmyocardial Revascularization

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, including port access procedures using novel robotic and thoracoscopic techniques.

Percutaneous Transmyocardial Revascularization

TMR can also be performed as percutaneous TMR (PTMR). PTMR (also called percutaneous myocardial channeling) is a catheter-based system using holmium: yttrium-aluminum garnet 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, PTMR has potential disadvantages. To minimize the risks 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.

Other potential applications of TMR include its use as an adjunct to stem cell-based therapy.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and the ability to function - including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant,

studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Open Transmyocardial Revascularization in Patients with Inoperable Coronary Artery Disease

Clinical Context and Therapy Purpose

The purpose of transmyocardial revascularization (TMR) for the treatment of angina refractory to medical therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with angina refractory to medical therapy.

Interventions

The therapy being considered is TMR performed via a thoracotomy, with the patient under general anesthesia. Cardiopulmonary bypass is not required.

Comparators

The following therapies and practices are currently being used: continued medical therapy.

Outcomes

The general outcomes of interest include disease-specific survival (DSS), symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

A 2009 Cochrane review included RCTs assessing TMR in patients with grade III or IV angina who were excluded from other revascularization procedures.[2,] In the 7 studies of TMR that met inclusion

criteria, while the improvement in angina was greater in treated patients than in control patients (30-day mortality was greater in the TMR group), 1-year mortality was similar between the groups. Reviewers concluded there was insufficient evidence to determine whether the clinical benefits of TMR outweighed the potential risks. This Cochrane review was updated in 2015 with a search of the literature through 2014.[3] Reviewers included the same 7 studies of TMR (N=1137 participants; n=559 randomized to TMR). While angina classes improved by at least 2 classes in the TMR group (43.8% vs. 14.8%; odds ratio [OR], 4.63; 95% confidence interval [CI], 3.43 to 6.25), there were no significant differences in 30-day or in 1-year mortality in the intention-to-treat (ITT) analysis between groups. However, in the as-treated analysis, 30-day mortality was higher in the TMR group due to higher mortality in individuals who crossed over to TMR treatment (pooled OR =3.76; 95% CI, 1.63 to 8.66). Reviewers concluded: "This review shows that risks associated with TMLR [transmyocardial laser revascularization] outweigh the potential clinical benefits."

Randomized Controlled Trials

Since 1998, 3 RCTs with similar designs have been published. Schofield et al (1999) randomized 188 patients with refractory angina to TMR via a high-energy carbon dioxide (CO_2) laser or medical management alone.[4] At 12 months, 25% of the patients assigned to TMR improved by at least 2 Canadian Cardiovascular Society (CCS) anginal classes, compared with only 4% in the medical management group (p<.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 lower than in 3 RCTs published prior to 1998.[5,6,7] There was 5% perioperative mortality for the TMR group, and that group had a lower overall survival (OS) rate at 12 months (89%) than the medical management group (96%), but this difference was not statistically significant (p=.14).

Aaberge et al (2000) compared 50 patients randomized to pulsed CO_2 laser TMR with 50 patients randomized to medical management.[8] At 12 months, 39% of the TMR patients improved by at least 2 New York Heart Association anginal classes versus 0% in the medical management group (both the New York Heart Association and CCS contain 4 anginal classes, but class 1 in the New York Heart Association system permits no symptoms, potentially making a 2-class improvement more difficult to achieve). Exercise capacity did not improve using TMR. There was a 4% perioperative mortality rate with lower OS at 12 months in the TMR group (88% vs. 92%, respectively), but this difference was not statistically significant.

Jones et al (1999) randomized 86 patients with refractory angina to TMR with a holmium: yttrium-aluminum garnet (YAG) laser or to medical management.[9] 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 seconds vs. 294 seconds, respectively, p<.001). There was only 1 perioperative death in the TMR group, but OS data were not provided.

These 3 studies differ from the previously published 3 trials in that fewer patients improved by at least 2 anginal classes, suggesting that the magnitude of benefit may be lower than in the first 3 trials. These trials did not provide conclusive evidence on whether TMR improves survival or exercise capacity. Patient selection criteria based on the data are as follows:

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

Observational Studies

Peterson et al (2003) reported on utilization and outcomes for TMR from registry data of 173 hospitals participating in the Society for Thoracic Surgeons National Cardiac Database.[10,] The registry included 661 patients who underwent TMR alone for refractory angina.[10,11,] The study by Peterson et al (2003) 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 (e.g., unstable angina, recent MI).[11,] 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<.05), while patients with 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<.05). Finally, Allen et al (2004)[12,] reported on the 5-year results of their 1999 trial.[7,] At 5 years, the significant anginal relief observed 12 months after TMR alone was sustained long-term and continued to be superior to that observed for patients on continued medical management alone.

Section Summary: Open Transmyocardial Revascularization in Patients with Inoperable Coronary Artery Disease

For individuals with severe angina refractory to medical treatment who are not candidates for surgical revascularization, RCTs comparing TMR with medical therapy have demonstrated improvements in angina symptoms. The available study designs raise some concern that the effect seen could be related to placebo effects. However, for patients without other treatment options, TMR may be an option.

Open Transmyocardial Revascularization as an Adjunct to Coronary Artery Bypass Graft

Clinical Context and Therapy Purpose

The purpose of TMR for the treatment of individuals with coronary artery disease (CAD) undergoing coronary artery bypass graft (CABG) with areas of the myocardium that cannot be revascularized is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with CAD undergoing CABG with areas of the myocardium that cannot be revascularized.

Interventions

The therapy being considered is TMR performed via a thoracotomy, with the individual under general anesthesia. Cardiopulmonary bypass is not required.

Comparators

The following therapies and practices are currently being used: CABG without TMR.

Outcomes

The general outcomes of interest include OS, DSS, symptoms, morbid events, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Campbell et al. (2008) conducted a systematic review of TMR and percutaneous TMR (PTMR) for refractory angina pectoris as part of the development of guidelines from the National Institute of Health and Care Excellence.[13,] Reviewers evaluated 16 RCTs (10 TMR, 6 PTMR) and 13 nonrandomized studies (8 TMR, 5 PTMR); they concluded TMR and PTMR were not effective in treating refractory angina and did not improve objective measures of MI (i.e., myocardial perfusion tests and LVEF) or 12-month survival. While subjective, patient-reported outcomes showed some improvement with TMR and PTMR, reviewers noted improvements in angina symptoms and exercise tolerance were lost or reduced when blinding of treatment occurred. Reviewers found the risks of mortality and adverse events raised safety concerns. Additionally, reviewers noted most studies were conducted in the United States on male patients and, therefore, evidence on outcomes lacks application to wider populations.

A meta-analysis of 7 randomized trials by Liao et al. (2005) (N =1 053 patients) concluded, at 1-year follow-up, that TMR produced a significant improvement in angina class but no improvement in survival.[14,]

Section Summary: Open Transmyocardial Revascularization as an Adjunct to Coronary Artery Bypass Graft

Similar to the case of TMR as a stand-alone treatment, some trials of TMR as an adjunct to CABG have shown improvements in angina symptoms, although results are mixed.

Percutaneous Transmyocardial Revascularization

Clinical Context and Therapy Purpose

The purpose of PTMR for the treatment of angina refractory to medical therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with angina refractory to medical therapy.

Interventions

The therapy being considered is PTMR. Cardiopulmonary bypass is not required.

Comparators

The following therapies and practices are currently being used: continued medical therapy.

Outcomes

The general outcomes of interest include DSS, symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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

Review of Evidence

Systematic Reviews

A meta-analysis by McGillion et al (2010) evaluated 7 RCTs comparing PTMR with maximally tolerated antianginal therapy management.[15,] A total of 1213 patients with CCS class III or IV angina refractory to optimal medical management were included in the trials analyzed. Exclusion criteria included recent MI, aortic stenosis, mechanical aortic valve, peripheral vascular disease precluding catheter insertion, LVEF less than 25% to 30%, and myocardial wall thickness in laser-targeted areas of less than 8 to 9 mm. All patients randomized to PTMR groups in the trials received low-dose holmium:YAG lasers except for 1 arm of 1 trial, which used 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 were analyzed and data from 3 trials demonstrated that PTMR significantly reduced angina symptoms by at least 2 CCS classes (pooled OR =2.13; 95% CI, 1.22 to 3.73). PTMR also significantly improved self-reported, health-related quality of life, as measured by the Seattle Angina Questionnaire. For angina frequency, the standardized mean difference was 0.29 (95% CI, 0.05 to 0.52); for disease perception, the standardized mean difference was 0.37 (95% CI, 0.14 to 0.61); and for physical limitations, it was 0.29 (95% CI, 0.05 to 0.53) (n=2 studies). Significant differences were not found for patient-reported angina stability, treatment satisfaction, exercise duration, or all-cause mortality. In the only trial using blinded outcomes assessment (the phase 2 direct myocardial revascularization to improve angina symptoms in patients with severe coronary disease trial , reported by Leon et al. [2005]), there were no significant differences between treatment and control groups in improvement in angina class, change in exercise duration, or improvement in quality of life.[16,]

This meta-analysis suggested that PTMR may have benefits similar to open TMR, but conclusions were limited. Although 7 trials were included in the review, results for each outcome were based on only 2 or 3 studies. The findings of outcome benefits on combined analysis were not robust, because the addition of a third treatment arm from 1 trial eliminated the significant findings. Sensitivity analysis was not performed by study quality, the presence of blinding, the presence of a sham placebo, or trial design measures that might have helped determine whether group differences reported in some trials were due to a treatment effect or a placebo/nonspecific effect. Reviewers identified a need for further studies to evaluate adverse events, disease-specific mortality, laser dosages, and underlying mechanisms of PTMR.

In another systematic review, Campbell et al (2008) concluded PTMR was not an effective treatment for refractory angina pectoris.[13,]

Randomized Controlled Trials

The following are examples of RCTs included in the McGillion et al (2010) meta-analysis[15,] (previously discussed), which compared PTMR with medical management. In the Potential Angina Class Improvement From Intramyocardial Channels trial, Oesterle et al. (2000) compared PTMR (n=110) with medical management (n=111) in patients with refractory angina.[17,] Several patients in the PTMR group (n=10) and the medical management group (n=14) received percutaneous transluminal coronary angioplasty, CABG, or TMR within the 12-month follow-up period. When these patients were included in a 12-month analysis, 46% in the PTMR group improved by at least 2 CCS anginal classes compared with 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 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

were more deaths at 12 months in the PTMR group, but the difference was not statistically significant (8 vs. 3, p=.21).

In the second published RCT, Stone et al. (2002) studied 141 patients with refractory angina and 1 or more chronic total occlusions in territories with reversible ischemia.[18,] This trial group was derived from a larger group of patients in whom percutaneous transluminal coronary angioplasty of a chronic total occlusion was attempted. If percutaneous transluminal coronary angioplasty was not possible, patients were immediately randomized to PTMR (n=71) or to 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=.33). There was a small increase in exercise duration in the PTMR group (64 seconds) over the sham group (52 seconds) that was also not statistically significant (p=.73). There was no difference in mortality at 6 months between groups (8.6% vs. 8.8%, p=.91). The trialists concluded that the similar degree of benefit in the sham group compared with the PTMR group suggested that improvement from PTMR might have been largely due to a placebo effect.

Section Summary: Percutaneous Transmyocardial Revascularization

RCTs of PTMR have shown some improvements in refractory angina symptoms, but some trial analyses have suggested that those results may have been due to the placebo effect.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association and American College of Cardiology

In 2012, guidelines for stable ischemic heart disease (SIHD) were developed by the American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and 6 other cardiovascular medical associations.[19,] As an alternative therapy for "relief of symptoms in patients with refractory angina… transmyocardial revascularization (TMR) may be considered for relief of refractory angina in patients with SIHD" (Class IIb recommendation, level of evidence B; benefit greater than risk, evidence less well-established). These guidelines indicated TMR may be considered as an alternative therapy for refractory angina in patients with stable ischemic heart disease. In 2017, the AHA and 7 other cardiovascular medical associations released guidelines for appropriate use criteria for coronary revascularization in patients with SIHD, but there was no mention of TMR. [20,]The 2012 SIHD guidelines were updated in 2023 to guidelines for the management of patients with chronic coronary disease.[21,] Based on a thorough review of the available evidence, the 2023 writing committee decided a recommendation related to TMR is no longer warranted, and did not reaffirm the 2b recommendation from 2012.

The American College of Cardiology and AHA (2011) published guidelines for coronary artery bypass surgery [22,] and percutaneous artery intervention .[23,]These guidelines both indicated that TMR may be performed as an adjunct to coronary artery bypass surgery on viable ischemic myocardium that is perfused by arteries not amenable to grafting (class IIb, level of evidence B: benefit greater than risk, evidence less well-established). These guidelines were consolidated and updated in 2021 as a guideline for coronary artery revascularization.[24,] This guideline did not mention the use of TMR or percutaneous TMR (PTMR) explicitly.

National Institute for Health and Care Excellence

In 2009, NICE issued guidance on TMR[25,] and PTMR [26,] based on the 2008 systematic review by Campbell et al (noted earlier).[13,] The guidance on TMR stated: "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 guidance for percutaneous TMR stated: "Current evidence on percutaneous laser revascularization for refractory angina pectoris shows no efficacy and suggests that the procedure may pose unacceptable safety risks."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare and Medicare Services[27,]:

"covers TMR as a late or last resort for patients with severe (Canadian Cardiovascular Society classification Classes III or IV) angina (stable or unstable), which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages." In addition, the angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty, stenting, coronary atherectomy, or coronary bypass. Coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the U.S. Food and Drug Administration for the purpose for which they are being used.

Patients would have to meet the following additional selection guidelines:

- "An ejection fraction of 25% or greater;
- Have areas of viable ischemic myocardium (as demonstrated by diagnostic study) which are not capable of being revascularized by direct coronary intervention; and
- Have been stabilized, or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure, or acute myocardial infarction."

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01827319[a]	A Multi-Center Single Arm Observational Registry of the Cardiogenesis Holmium: YAG Laser System Transmyocardial Revascularization for Angina Reduction [There is an agreement between PIs and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.]	203	Jun 2015 (completed)

NCT: national clinical trial; PI: principal investigator; YAG: yttrium-aluminum garnet.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Laham RJ, Simons M. Transmyocardial laser revascularization for management of refractory angina. In: Aldea GS, Verrier E, Gersh BJ, ed. UpToDate. Waltham, MA: UpToDate Inc.;

February 2023. https://www.uptodate.com/contents/transmyocardial-laser-revascularization-for-management-of-refractory-angina. Accessed January 3, 2024.
2. Briones E, Lacalle JR, Marin I. Transmyocardial laser revascularization versus medical therapy for refractory angina. Cochrane Database Syst Rev. Jan 21 2009; (1): CD003712. PMID 19160223
3. Briones E, Lacalle JR, Marin-Leon I, et al. Transmyocardial laser revascularization versus medical therapy for refractory angina. Cochrane Database Syst Rev. Feb 27 2015; 2015(2): CD003712. PMID 25721946
4. Schofield PM, Sharples LD, Caine N, et al. Transmyocardial laser revascularisation in patients with refractory angina: a randomised controlled trial. Lancet. Feb 13 1999; 353(9152): 519-24. PMID 10028979
5. 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. Sep 30 1999; 341(14): 1021-8. PMID 10502591
6. 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. Sep 11 1999; 354(9182): 885-90. PMID 10489946
7. Allen KB, Dowling RD, Fudge TL, et al. Comparison of transmyocardial revascularization with medical therapy in patients with refractory angina. N Engl J Med. Sep 30 1999; 341(14): 1029-36. PMID 10502592
8. 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. Apr 2000; 35(5): 1170-7. PMID 10758957
9. Jones JW, Schmidt SE, Richman BW, et al. Holmium:YAG laser transmyocardial revascularization relieves angina and improves functional status. Ann Thorac Surg. Jun 1999; 67(6): 1596-601; discussion 1601-2. PMID 10391261
10. Peterson ED, Kaul P, Kaczmarek RG, et al. From controlled trials to clinical practice: monitoring transmyocardial revascularization use and outcomes. J Am Coll Cardiol. Nov 05 2003; 42(9): 1611-6. PMID 14607448
11. Saririan M, Eisenberg MJ. Myocardial laser revascularization for the treatment of end-stage coronary artery disease. J Am Coll Cardiol. Jan 15 2003; 41(2): 173-83. PMID 12535804
12. Allen KB, Dowling RD, Angell WW, et al. Transmyocardial revascularization: 5-year follow-up of a prospective, randomized multicenter trial. Ann Thorac Surg. Apr 2004; 77(4): 1228-34. PMID 15063241
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. 2008 November http://www.nice.org.uk/guidance/ipg302/documents/systematic-review-of-the-efficacy-and-safety-of- transmyocardial-and-percutaneous-laser-revascularisation-for-refractory-angina-pectoris2. Accessed January 3, 2024.
14. Liao L, Sarria-Santamera A, Matchar DB, et al. Meta-analysis of survival and relief of angina pectoris after transmyocardial revascularization. Am J Cardiol. May 15 2005; 95(10): 1243-5. PMID 15878002
15. McGillion M, Cook A, Victor JC, et al. Effectiveness of percutaneous laser revascularization therapy for refractory angina. Vasc Health Risk Manag. Sep 07 2010; 6: 735-47. PMID 20859544
16. Leon MB, Kornowski R, Downey WE, et al. A blinded, randomized, placebo-controlled trial of percutaneous laser myocardial revascularization to improve angina symptoms in patients with severe coronary disease. J Am Coll Cardiol. Nov 15 2005; 46(10): 1812-9. PMID 16286164
17. Oesterle 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. Nov 18 2000; 356(9243): 1705-10. PMID 11095257

18. 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. May 15 2002; 39(10): 1581-7. PMID 12020483
19. 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. Dec 18 2012; 60(24): e44-e164. PMID 23182125
20. Patel MR, Calhoon JH, Dehmer GJ, et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease : A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. J Nucl Cardiol. Oct 2017; 24(5): 1759-1792. PMID 28608183
21. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. Aug 29 2023; 148(9): e9-e119. PMID 37471501
22. 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. Dec 06 2011; 58(24): e123-210. PMID 22070836
23. 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. Dec 06 2011; 58(24): e44-122. PMID 22070834
24. Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. Jan 18 2022; 145(3): e18-e114. PMID 34882435
25. National Institute for Health and Care Excellence. Transmyocardial laser revascularisation for refractory angina pectoris [IPG301]. 2009; https://www.nice.org.uk/guidance/ipg301. Accessed January 2, 2024.
26. National Institute for Health and Care Excellence. Percutaneous laser revascularisation for refractory angina pectoris [IPG302]. 2009; https://www.nice.org.uk/guidance/ipg302. Accessed January 3, 2024.
27. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6). 1999; https://www.cms.gov/medicare-coverage-database/details/ncd- details.aspx?NCDId=120&ncdver=1&bc=BAABAAAAAAAA&. Accessed January 3, 2024.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities

  - Activity and functional limitations
  - Family history if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (e.g., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management) when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	33140	Transmyocardial laser revascularization, by thoracotomy; (separate procedure)
	33141	Transmyocardial laser revascularization, by thoracotomy; performed at the time of other open cardiac procedure(s) (List separately in addition to code for primary procedure)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/30/2015	BCBSA Medical Policy Adoption
04/01/2016	Policy revision with no position change
02/01/2017	Coding update
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
04/01/2019	Policy revision without position change
05/01/2024	Policy reactivated. Previously archived from 05/01/2020 to 04/30/2024.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Reactivated Policy **Policy Statement:** N/A	**Transmyocardial Revascularization 7.01.54** **Policy Statement:** I. Transmyocardial laser revascularization may be considered **medically necessary** for individuals with class III or IV angina, who are not candidates for coronary artery bypass graft surgery or percutaneous transluminal coronary angioplasty surgery, who 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 30% D. No evidence of recent myocardial infarction or unstable angina within the last 21 days E. No severe comorbid illness such as chronic obstructive pulmonary disease II. Transmyocardial laser revascularization may be considered **medically necessary** as an adjunct to coronary artery bypass graft in those individuals with documented areas of ischemic myocardium that are not amenable to surgical revascularization. III. Transmyocardial laser revascularization is considered **investigational** for all other indications not meeting the above criteria. IV. Percutaneous transmyocardial laser revascularization is considered **investigational**.