Transmyocardial Revascularization

Policy Number: 7.01.54  
Last Review: 5/2018  
Origination: 5/2003  
Next Review: 5/2019

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for transmyocardial revascularization when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Open transmyocardial laser revascularization 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 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, and
- No severe co-morbid illness such as chronic obstructive pulmonary disease (COPD)

Open transmyocardial laser revascularization may be considered medically necessary 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.

When Policy Topic is not covered
Percutaneous transmyocardial laser revascularization is considered investigational.

Open transmyocardial laser revascularization is considered investigational for all other indications not meeting the above criteria.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
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</table>
| Individuals:  
• With class III or IV angina refractory to medical treatment | Interventions of interest are:  
• Transmyocardial revascularization | Comparators of interest are:  
• Medical treatment | Relevant outcomes include:  
• Disease-specific survival  
• Symptoms  
• Functional outcomes  
• Health status measures |
Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization, is a surgical technique that attempts to improve blood flow to ischemic heart muscle by creating direct channels from the left ventricle into the myocardium. TMR may be performed via a thoracotomy or percutaneous TMR (PTMR).

For individuals who have class III or IV angina refractory to medical treatment who receive TMR, the evidence includes several randomized controlled trials (RCTs). Relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and treatment-related morbidity. The available RCTs have demonstrated that TMR may provide significant improvements in angina symptoms compared with optimal medical management, but not in survival outcomes or other objective outcomes. The unblinded design of the RCTs with subjective outcomes raises concern about bias. In addition, all of the studies of TMR were conducted in an era prior to the availability of drug-eluting stents, and some were notable for unexpectedly high mortality rates in the control groups. Although studies have not shown improvements in survival or significant increases in exercise duration, the improvement in symptoms represents a health benefit for patients with class III or IV angina who are not candidates for revascularization, who are refractory to medical management, who have reversible ischemia, and who have a left ventricular ejection fraction greater than 30%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have coronary artery disease and are undergoing coronary artery bypass graft with documented areas of ischemic myocardium that cannot be surgically revascularized who receive TMR as adjunctive treatment, the evidence

<table>
<thead>
<tr>
<th>Individuals:</th>
<th>Interventions of interest are:</th>
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<tbody>
<tr>
<td>With coronary artery disease undergoing coronary artery bypass graft with areas of myocardium that cannot be revascularized</td>
<td>Transmyocardial revascularization as adjunctive treatment</td>
<td>Coronary artery bypass graft without transmyocardial revascularization</td>
<td>Overall survival, Disease-specific survival, Symptoms, Morbid events, Functional outcomes, Health status measures, Quality of life, Hospitalizations, Treatment-related mortality, Treatment-related morbidity</td>
</tr>
<tr>
<td>With class III or IV angina refractory to medical treatment</td>
<td>Percutaneous transmyocardial revascularization</td>
<td>Medical treatment</td>
<td>Disease-specific survival, Symptoms, Functional outcomes, Health status measures, Quality of life, Treatment-related mortality, Treatment-related morbidity</td>
</tr>
</tbody>
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includes meta-analyses of RCTs. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, health status measures, quality of life, hospitalizations, treatment-related mortality and treatment-related morbidity. Meta-analyses of these RCTs have reported an improvement in angina, but no improvement in mortality or other relevant outcomes. Similar to TMR as a stand-alone procedure, the unblinded design of the RCTs with subjective outcomes raises concern about bias, but the improvement suggests a health benefit to this patient population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have class III or IV angina refractory to medical treatment who receive PTMR, the evidence includes a number of RCTs. Relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life, treatment-related mortality and treatment-related morbidity. Although 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 robust in showing whether PTMR improves net health outcomes. Additionally, no U.S. Food and Drug Administration–approved PTMR devices are available. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

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 for TMR using novel robotic and thoracoscopic techniques.

Transmyocardial revascularization can also be performed by the percutaneous route (PTMR). PTMR (now being called percutaneous myocardial channeling or PMC) is a catheter-based 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 is not amenable to surgical revascularization. Other potential applications of TMR include its use as an adjunct to stem-cell based therapy.

**Regulatory Status**
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.

**Rationale**
This evidence review was created in May 1997 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through December 11, 2017.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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.

**Open Transmyocardial Revascularization**
This portion of the evidence review was informed in part on 2 TEC Assessments, a 1998 Assessment that focused on the use of open transmyocardial revascularization (TMR; or transmyocardial laser revascularization) as an
alternative to inoperable coronary artery disease, and a 2001 Assessment\(^3\) that focused on its use as an adjunct to coronary artery bypass surgery (CABG).

**TMR in Patients With Inoperable Coronary Artery Disease**

**Systematic Reviews**

The 1998 TEC Assessment offered the following observations and conclusions on the available RCTs (described in detail in the Randomized Controlled Trials section)\(^2\):

“Results of randomized controlled 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 favored 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 across the trials and have evolved in response to recognition of high-risk subgroups among the initial RCTs. In general, 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.

A 2009 Cochrane review included RCTs assessing TMR in patients with grade III or IV angina who were excluded from other revascularization procedures.\(^4\) 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 that 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.\(^5\) Reviewers included the same 7 studies of TMR (total N=1137 participants; 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 analysis between groups. However, in 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**

The 3 unpublished RCTs cited in the original TEC Assessment\(^2\) have since been published.\(^6\)\(^-\)\(^9\) Since then, three other RCTs with similar designs have been published. Schofield et al (1999) randomized 188 patients with refractory angina to TMR via a high-energy CO\(_2\) laser or medical management alone.\(^9\) 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<0.001). There were no statistically significant differences in exercise duration, 12-minute walk distance, or radionuclide perfusion. The number of patients improving by two or more angina classes was much lower than in the three previously cited RCTs. There was 5% perioperative mortality for the TMR group and that group had a lower overall survival rate at 12 months (89%) than the medical management group (96%; p=0.14), but this difference was not statistically significant.

Aaberge et al (2000) compared 50 patients randomized to pulsed CO\(_2\) laser TMR with 50 patients randomized to medical management.\(^10\) At 12 months, 39% of the TMR patients improved by at least 2 New York Heart Association anginal classes vs 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 overall survival 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:YAG laser or to medical management.\(^11\) 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<0.001). There was only 1 perioperative death in the TMR group, but OS data were not provided.

These 3 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 lower than in the first 3 trials. These trials did not provide conclusive evidence 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 greater than 30%
- No evidence of recent MI or unstable angina within the last 21 days
- No severe comorbid illness such as chronic obstructive pulmonary disease.

**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. The registry included 661 patients who underwent TMR alone for refractory angina. 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 (eg, unstable angina, 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 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 (2004) reported on the 5-year results of their 1999 trial. 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: TMR 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 options, TMR may be an option.

**Open TMR as an Adjunct to CABG**

The 2001 TEC Assessment offered the following observations and conclusions about 2 randomized, single-blind trials that compared outcomes of patients who underwent CABG alone with 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 was statistically significant in the second larger trial, enrolling 266 patients. In the larger trial, perioperative mortality was 7.5% in the control group and 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).

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. 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 (ie, myocardial perfusion tests and left ventricular ejection fraction) 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; total N=1053 patients) concluded, at 1-year follow-up, that TMR produced a significant improvement in angina class but no improvement in survival.\textsuperscript{16}

**Section Summary: TMR as an Adjunct to CABG**

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**

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 be considered as distinct entities.

**Systematic Reviews**

For the 1998 TEC Assessment,\textsuperscript{2} no outcomes data on PTMR were available, although 2003 observational data suggested that the symptomatic benefit of PTMR approached that seen with TMR.\textsuperscript{12} As noted, in a systematic review, Campbell et al (2008) concluded PTMR was not an effective treatment for refractory angina pectoris.\textsuperscript{15}

A meta-analysis by McGillion et al (2010) evaluated 7 RCTs comparing PTMR with maximally tolerated antianginal therapy management.\textsuperscript{17} 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, left ventricular ejection fraction 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 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 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 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.  

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, presence of blinding, or the presence of a sham placebo, 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.

Randomized Controlled Trials
The following are examples of RCTs included in the McGillion 2010 meta-analysis (previously discussed), which compared PTMR with medical management. In the PACIFIC trial, Oesterle et al (2000) compared PTMR (n=110) with medical management (n=111) in patients with refractory angina. 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=0.21).

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. 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 vs 37% in the sham group. This difference was not statistically significant (p=0.33). 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=0.73). There was no difference in mortality at 6 months between groups (8.6% vs 8.8%, p=0.91). 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 placebo effect.

Summary of Evidence
For individuals who have class III or IV angina refractory to medical treatment who receive TMR, the evidence includes several RCTs. Relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and treatment-related morbidity. The available RCTs have demonstrated that TMR may provide significant improvements in angina symptoms compared with optimal medical management, but not in survival outcomes or other objective outcomes. The unblinded design of the RCTs with subjective outcomes raises concern about bias. In addition, all of the studies of TMR were conducted in an era prior to the availability of drug-eluting stents, and some were notable for unexpectedly high mortality rates in the control groups. Although studies have not shown improvements in survival or significant increases in exercise duration, the improvement in symptoms represents a health benefit for patients with class III or IV angina who are not candidates for revascularization, who are refractory to medical management, who have reversible ischemia, and who have a left ventricular ejection fraction greater than 30%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have coronary artery disease and are undergoing CABG with documented areas of ischemic myocardium that cannot be surgically revascularized who receive TMR as adjunctive treatment, the evidence includes meta-analyses of RCTs. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, health status measures, quality of life, hospitalizations, treatment-related mortality and treatment-related morbidity. Meta-analyses of these RCTs have reported an improvement in angina, but no improvement in mortality or other relevant outcomes. Similar to TMR as a stand-alone procedure, the unblinded design of the RCTs with subjective outcomes raises concern about bias, but the improvement suggests a health benefit to this patient population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have class III or IV angina refractory to medical treatment who receive PTMR, the evidence includes a number of RCTs. Relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life, treatment-related mortality and treatment-related morbidity. Although 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 robust in showing whether PTMR improves the net health outcome. Additionally, no U.S. Food and Drug Administration–approved PTMR devices are available. The evidence is insufficient to determine the effects of the technology on health outcomes.
Supplemental Information

Practice Guidelines and Position Statements

American College of Cardiology Foundation et al
In 2012, guidelines for stable ischemic heart disease (SIHD) were developed by the American College of Cardiology Foundation and 6 other cardiovascular medical associations. 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 SIHD (class IIb, level of evidence B: benefit greater than risk, evidence less well-established).

In 2011, the American College of Cardiology Foundation and the American Heart Association published guidelines for coronary artery bypass surgery (CABG) (with the Society of Thoracic Surgeons) and percutaneous artery intervention (with the Society for Cardiovascular Angiography and Interventions). These guidelines both indicated that TMR may be performed as an adjunct to CABG 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).

Society of Thoracic Surgeons
In 2004 (reaffirmed in 2009), the Society of Thoracic Surgeons published recommendations on open TMR; the recommendations did not discuss the percutaneous TMR (PTMR), although it was noted to be less promising than open TMR. The Society defined class I recommendations as conditions for which there is evidence or general agreement that a given procedure or treatment is useful and effective. There was 1 class I recommendation for TMR as solo therapy, as follows:

“Patients with an ejection fraction greater than 0.30 and CCS [Canadian Cardiovascular Society] 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 controlled trials. There were no class I recommendations for TMR combined with CABG. There was 1 class IIa recommendation, which defines conditions for which there is conflicting evidence or a divergence of opinion but for which the weight of
evidence or opinion favors usefulness or efficacy. The class IIa recommendation was 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 2000 randomized trial and data from the Society of Thoracic Surgeons National Cardiac Database. These 2 class I and IIa recommendations included positive recommendations for use in patients with refractory angina, and as an adjunct to CABG in appropriately selected patients.

**National Institute for Health and Care Excellence**

In 2009, the National Institute for Health and Care Excellence issued guidance on TMR and PTMR based on the 2008 systematic review by Campbell et al (noted earlier). 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 PTMR 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:

“cover 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 to perform the procedures that have been approved by the Food and Drug Administration for the purpose for which they are being used.

Patients would have to meet the following additional selection guidelines:

1. An ejection fraction of 25% or greater;
2. Have areas of viable ischemic myocardium (as demonstrated by diagnostic study) that are not capable of being revascularized by direct coronary intervention; and
3. 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**

<table>
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<th>Trial Name</th>
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<td>NCT01827319a</td>
<td>A Multi-Center Single Arm Observational Registry of the Cardiogenesis Holmium: YAG Laser System Transmyocardial Revascularization for Angina Reduction</td>
<td>204</td>
<td>Jun 2015 (completed)</td>
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NCT: national clinical trial.

*a Denotes industry-sponsored or cosponsored trial.

**References**


**Billing Coding/Physician Documentation Information**

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<tr>
<th>Code</th>
<th>Description</th>
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<td>33140</td>
<td>Transmyocardial laser revascularization</td>
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**ICD10 Codes**

<table>
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<th>Code</th>
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<td>I20.0-</td>
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</table>

CPT code 33140 (transmyocardial laser revascularization, separate procedure) describes transmyocardial laser revascularization used as a treatment of inoperable coronary artery disease (e.g., CABG, PTCA).

CPT code 33141 (transmyocardial laser revascularization at the time of other open cardiac procedures), introduced in 2001, principally describes the use of transmyocardial laser revascularization as an adjunct to CABG. Therefore this code will be used in conjunction with codes describing CABG procedures, i.e., codes 33400-33496, 33510-33536, and 33542.

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>5/1/03</td>
<td>New policy.</td>
</tr>
<tr>
<td>5/1/04</td>
<td>Policy statement revised to include specific criteria for coverage. Policy statement revised to include percutaneous transmyocardial laser revascularization as investigational.</td>
</tr>
<tr>
<td>5/1/05</td>
<td>No policy statement changes.</td>
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<tr>
<td>5/1/06</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/07</td>
<td>No policy statement changes.</td>
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<td>5/1/08</td>
<td>No policy statement changes.</td>
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<tr>
<td>5/1/09</td>
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<td>5/1/11</td>
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<tr>
<td>5/1/13</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/14</td>
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</table>
5/1/15  Policy statement added indicating open TMR is considered investigational for all other indications not meeting the medical necessity criteria.
5/1/16  No policy statement changes.
5/1/17  No policy statement changes.
5/1/18  No policy statement changes.

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