Medical Policy
Transmyocardial Revascularization

Table of Contents
- Policy: Commercial
- Coding Information
- Information Pertaining to All Policies
- Policy: Medicare
- Description
- References
- Authorization Information
- Policy History

Policy Number: 651
BCBSA Reference Number: 7.01.54
NCD/LCD: National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6)

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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 myocardial infarction or unstable angina within the last 21 days
- No severe comorbid illness such as chronic obstructive pulmonary disease (COPD)

Open transmyocardial laser revascularization may be 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.

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

Percutaneous transmyocardial laser revascularization is considered INVESTIGATIONAL.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

CMS therefore 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 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) which 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.

Coverage is limited to physicians who have been properly trained in the procedure. Providers of this service must also document that all ancillary personnel, including physicians, nurses, operating room personnel and technicians, are trained in the procedure and the proper use of the equipment involved. Coverage is further limited to providers which have dedicated cardiac care units, including the diagnostic and support services necessary for care of patients undergoing this therapy. In addition, these providers must conform to the standards for laser safety set by the American National Standards Institute, ANSIZ1363.

National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6)

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

| Commercial Managed Care (HMO and POS) | Yes |
| Commercial PPO and Indemnity | Yes |
| Medicare HMO Blue℠ | Yes |
| Medicare PPO Blue℠ | Yes |

CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33140</td>
<td>Transmyocardial laser revascularization, by thoracotomy; (separate procedure)</td>
</tr>
<tr>
<td>33141</td>
<td>Transmyocardial laser revascularization, by thoracotomy; performed at the time of other open cardiac procedure(s) (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>
ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>021L0Z5</td>
<td>Bypass Left Ventricle To Coronary Circulation, Open Approach</td>
</tr>
</tbody>
</table>

**Description**

**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 (CABG) 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. Various port access procedures are being evaluated for TMR using novel robotic and thoracoscopic techniques.

**PERCUTANEOUS TMR**

TMR can also be performed percutaneously (ie, percutaneous TMR [PTMR]). PTMR (also called percutaneous myocardial channeling) is a catheter-based system using holmium: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, 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 (eg, 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.

**Summary**

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).

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 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.

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>2/2014</td>
<td>Coding information clarified.</td>
</tr>
<tr>
<td>12/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
<tr>
<td>11/2013</td>
<td>Changed prior authorization information as prior authorization has always been required for this policy.</td>
</tr>
<tr>
<td>2/2012</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
</tr>
<tr>
<td>12/2008</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
</tr>
</tbody>
</table>

### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
References


