**Transmyocardial Revascularization**

(70154)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 01/01/15</th>
<th>Next Review Date: 09/18</th>
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<tbody>
<tr>
<td>Preauthorization</td>
<td>Yes</td>
<td>Review Dates: 01/08, 01/09, 01/10, 01/11, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17</td>
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**Preauthorization is required.**

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals: • With class III or IV angina refractory to medical treatment</td>
<td>Interventions of interest are: • Transmyocardial revascularization</td>
<td>Comparators of interest are: • Medical treatment</td>
<td>Relevant outcomes include: • Disease-specific survival • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality • Treatment-related morbidity</td>
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<tr>
<td>Individuals: • With coronary artery disease undergoing coronary artery bypass graft with areas of myocardium that cannot be revascularized</td>
<td>Interventions of interest are: • Transmyocardial revascularization as adjunctive treatment</td>
<td>Comparators of interest are: • Coronary artery bypass graft without transmyocardial revascularization</td>
<td>Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events • Functional outcomes • Health status measures • Quality of life • Hospitalizations • Treatment-related mortality • Treatment-related morbidity</td>
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<tr>
<td>Individuals: • With class III or IV angina refractory to medical treatment</td>
<td>Interventions of interest are: • Percutaneous transmyocardial revascularization</td>
<td>Comparators of interest are: • Medical treatment</td>
<td>Relevant outcomes include: • Disease-specific survival • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality • Treatment-related morbidity</td>
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**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 transmyocardial revascularization (PTMR).

Summary of Evidence

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 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.

Policy

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 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 greater than 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
Open transmyocardial laser revascularization may be considered medically necessary as an adjunct to CABG in those patients with documented areas of ischemic myocardium that are not amenable to surgical revascularization.

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

Percutaneous transmyocardial laser revascularization is considered investigational.

**Medicare Advantage**

In addition or in place of the above policy guidelines, ejection fraction can be 25% or greater and patients need to be stable or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

CMS covers TMR as a late or last resort for patients with severe angina 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.

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

TMR can also be performed percutaneously (i.e., percutaneous transmyocardial revascularization [PTMR]). PTMR (now being 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. 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.

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

**Regulatory Status**

In 1998, the Heart Laser™ was approved by the U.S. Food and Drug Administration (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 FDA through the premarket approval
process for similar indications. Neither device is approved for use as an adjunct to coronary artery bypass graft. Use of either device for this purpose would be considered an off-label indication. PMA product code: MNO.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


