FEP Medical Policy Manual

FEP 7.01.54 Transmyocardial Revascularization

Effective Policy Date: July 1, 2019

Original Policy Date: September 2012

Related Policies:
None

Transmyocardial Revascularization

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).

OBJECTIVE

The objective of this evidence review is to evaluate whether transmyocardial revascularization improves the net health outcome as a stand-alone procedure or an adjunct to coronary artery bypass graft in individuals with coronary ischemia.

POLICY STATEMENT

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 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

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● No severe comorbid illness such as chronic obstructive pulmonary disease.

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

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

Percutaneous transmyocardial laser revascularization is considered investigational.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Bundling or multiple surgery guidelines should apply.

**FDA 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**

**Summary of Evidence**

For individuals who have class III or IV angina refractory to medical treatment who receive TMR, the evidence includes several RCTs. The relevant outcomes are DSS, symptoms, functional outcomes, health status measures, QOL, and TRM 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 CAD 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. The relevant outcomes are OS, DSS, symptoms, morbid events, functional outcomes, health status measures, QOL, hospitalizations, TRM, 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. The relevant outcomes are DSS, symptoms, functional outcomes, health status measures, QOL, TRM and treatment-related morbidity. Although PTMR is less invasive than TMR and some studies have shown improvements in angina symptoms and health-related QOL, 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 technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Cardiology Foundation et al

In 2012, guidelines for stable ischemic heart disease were developed by the American College of Cardiology Foundation and 6 other cardiovascular medical associations.21 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 (class IIb, level of evidence B: benefit greater than risk, evidence less well-established).

The American College of Cardiology Foundation and the American Heart Association (2011) published guidelines for coronary artery bypass surgery22 (with the Society of Thoracic Surgeons) and percutaneous artery intervention (with the Society for Cardiovascular Angiography and Interventions).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).

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2009) issued guidance on TMR25 and percutaneous TMR26 based on the 2008 systematic review by Campbell et al (noted earlier).15 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 Services27:

"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."

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REFERENCES


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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New policy</td>
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<tr>
<td>December 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 11, 18-20 added. Not medically necessary statement in policy deleted.</td>
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<tr>
<td>December 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 20, 2014. Policy statement added indicating open TMR is considered investigational for all other indications not meeting the medical necessity criteria.</td>
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<tr>
<td>December 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 1, 2015; no references added. Policy statements unchanged.</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review; no references added. Policy statements unchanged.</td>
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<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through December 11, 2017; reference 1 added. Policy statement unchanged.</td>
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<td>June 2019</td>
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