FEP 7.01.54 Transmyocardial Revascularization

Effective Date: July 15, 2018 **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).

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 amendable 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 CABG. Use of either device for this purpose would be considered an off-label indication. FDA product code: MNO.

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
- 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).

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. 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.[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 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)[22] (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 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.[24] 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[25] and data from the Society of Thoracic Surgeons National Cardiac Database.[12] 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[26] and PTMR[27] 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 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[28]:

> "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.
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> 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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POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
December 2013	Update Policy	Policy updated with literature review; references 11, 18-20 added. Not medically necessary statement in policy deleted.
December 2014	Update Policy	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.
December 2015	Update Policy	Policy updated with literature review through July 1, 2015; no references added. Policy statements unchanged.
December 2016	Update Policy	Policy updated with literature review; no references added. Policy statements unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; reference 1 added. Policy statement unchanged