Protocol

Transmyocardial Revascularization

(70154)

Medical Benefit		**Effective Date**: 04/01/10	**Next Review Date**: 09/14
Preauthorization	Yes	**Review Dates**: 01/08, 01/09, 01/10, 01/11, 09/11, 09/12, 09/13	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *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.*

Description

Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization (TMLR), is a surgical technique that attempts to improve blood flow to ischemic heart muscle via the creation of direct channels from the left ventricle into the myocardium.

Background

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 to use TMR using novel robotic and thoracoscopic techniques.

TMR 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 two 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 CABG in patients with areas of ischemic myocardium that are not amenable to surgical revascularization. Other potential applications of TMR include its use as an adjunct to stem-cell based therapy.

The Heart Laser™ received final U.S. Food and Drug Administration (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.

Corporate Medical Guideline

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.

Percutaneous transmyocardial laser revascularization is considered **investigational**.

Medicare Advantage

In addition or in place of the above, 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.

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.

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