Protocol

Transmyocardial Revascularization

(70154)

Medical Benefit		**Effective Date**: 01/01/15	**Next Review Date**: 09/20
Preauthorization	No	**Review Dates**: 01/08, 01/09, 01/10, 01/11, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18, 09/19	

Preauthorization is not 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With class III or IV angina refractory to medical treatment	Interventions of interest are: • Transmyocardial revascularization	Comparators of interest are: • Medical treatment	Relevant outcomes include: • Disease-specific survival • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • With coronary artery disease undergoing coronary artery bypass graft with areas of myocardium that cannot be revascularized	Interventions of interest are: • Transmyocardial revascularization as adjunctive treatment	Comparators of interest are: • Coronary artery bypass graft without transmyocardial revascularization	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
Individuals: • With class III or IV angina refractory to medical treatment	Interventions of interest are: • Percutaneous transmyocardial revascularization	Comparators of interest are: • Medical treatment	Relevant outcomes include: • Disease-specific survival • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality • Treatment-related morbidity

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).

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). The relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life (QOL), 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. The relevant outcomes are overall survival (OS), disease-specific survival, symptoms, morbid events, functional outcomes, health status measures, QOL, 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. The relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, QOL, 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 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.

POLICY

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

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.

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 **medically necessary** 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 (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.

BACKGROUND

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

Percutaneous TMR

TMR can also be performed percutaneously (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 (e.g., 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.

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 demon-

strated 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.

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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