

Subject: Transmyocardial Revascularization
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Description/Scope

This document addresses transmyocardial revascularization.

Position Statement

Medically Necessary:

Open transmyocardial revascularization, also known as transmyocardial laser revascularization, is considered **medically necessary** for individuals with class III or class 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; **and**
- Documentation of reversible ischemia; **and**
- Left ventricular ejection fraction greater than 30%; **and**
- No evidence of recent myocardial infarction or unstable angina within the last 21 days; **and**
- No severe comorbid illness such as chronic obstructive pulmonary disease.

Open transmyocardial revascularization is considered **medically necessary** as an adjunct to coronary artery bypass graft in those individuals with documented areas of ischemic myocardium that are not amenable to surgical revascularization.

Investigational and Not Medically Necessary:

Percutaneous myocardial revascularization is considered **investigational and not medically necessary**.

All other uses of transmyocardial revascularization are considered **investigational and not medically necessary**.

Rationale

Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization (TMLR) involves the use of a high-energy laser beam to create transmural channels in the heart to allow oxygenated left ventricular blood to directly perfuse ischemic myocardium. TMR can be performed using an open thoracotomy approach or using a percutaneous approach where the laser can be inserted through the femoral artery. Open and percutaneous TMR have been used in individuals with end-stage coronary artery disease (CAD) that is refractory to medical therapy and who are not suitable candidates for alternative surgical interventions. These are persons with stable

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class III or class IV angina, who have hypoperfused but viable myocardium, who have failed medical management and are not amenable to traditional myocardial revascularization procedures, such as coronary artery bypass graft (CABG) and percutaneous transluminal coronary angioplasty (PTCA).

TMR has also been used in conjunction with CABG in some individuals with end-stage CAD that can be partially revascularized with CABG. The areas of ischemic myocardium not amenable to CABG are then treated by TMR, in conjunction with the standard CABG procedure. When performed in conjunction with CABG, an open approach is used.

A variety of randomized studies have consistently reported that open TMR, as a sole therapy in individuals with CAD who are not candidates for revascularization, is associated with a significant improvement in anginal symptoms. A meta-analysis of seven randomized trials involving 1053 participants concluded at 1 year follow-up, that TMR produced a significant improvement in anginal class but no improvement in survival (Liao, 2005). Since this large analytic review of the evidence, there has been limited published literature related to TMR procedures. However, the evidence continues to sufficiently demonstrate improved clinical outcomes in the subset of individuals with refractory angina who are not surgical candidates for traditional revascularization procedures.

One randomized, blinded trial evaluated the addition of open TMR to CABG. While there appeared to be a mortality benefit associated with combined TMR/CABG at 1 year (Allen, 2000), at 5 year follow-up survival was similar in both groups (Allen, 2004). However, the addition of TMR to CABG provided superior anginal relief compared to CABG alone. The American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) Guideline for Coronary Artery Bypass Graft Surgery (Hillis, 2011) recommends TMR as a Class IIb*** procedure, stating that TMR in combination with CABG is reasonable in individuals with angina that is refractory to medical therapy who are not candidates for percutaneous or open surgical revascularization. The medical necessity criteria for open TMR listed in the Position Statement section of this document are consistent with these guidelines. These guidelines do not make a distinction between open and percutaneous TMR. However, the randomized trials cited in support of the guideline recommendations all focused on open TMR.

Note: According to the ACCF/AHA guideline recommendations documents, the following are the definitions of Classifications of Recommendations, as expressed in the ACCF/AHA format:

- **Class I: Procedure/treatment should be performed/administered.
- *Class IIa: It is reasonable to perform procedure/administer treatment.
- ***Class IIb: Procedure/treatment may be considered.
- Class III (no benefit): Procedure/test is not helpful with; treatment no proven benefit.
- Class III (harm): Procedure/test has excess cost without benefit or harmful; treatment is harmful to individuals.

Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful (Hillis, 2011).

Percutaneous TMR was designed as a less invasive alternative to open TMR. Leon and colleagues published the results of a double-blind study that randomized 298 individuals with refractory angina to undergo percutaneous or

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sham TMR (Leon, 2005). Notably, myocardial “mapping” was obtained prior to the procedure to determine the electrical viability of treatment targets and to decide where to locate laser channels. The primary endpoint was the change in exercise duration from baseline to 6 months. At 6 months post-procedure, there were no significant differences in outcomes between the treatment groups and the placebo group, in part due to the pronounced placebo effect resulting in a 30% improvement in exercise duration and angina symptoms that was sustained for 12 months. This improvement was identical to that observed in the treatment arms. There was an increased rate of adverse clinical events associated with the laser treatment groups at 30 days. The authors note that blinded and unblinded randomized studies of percutaneous TMR have reported conflicting results, while the randomized studies of open TMR, all unblinded, have generally reported favorable results. Leon and colleagues suggest that a placebo effect may be responsible. There is insufficient evidence, to date, to demonstrate efficacy and the long-term outcomes of percutaneous TMR. McGillion and colleagues (2010) reported a meta-analysis of percutaneous myocardial laser revascularization (PMLR) and maximal medical therapy versus maximal medical therapy alone for refractory angina. A total of five trials were included in the final assessment (two trials initially included were excluded due to poor methodological quality) with a summarization of 12-month outcomes. The meta-analysis revealed that PMLR did not significantly improve exercise performance, however different approaches were used during each study to measure exercise performance. The meta-analysis also showed no significant overall impact on all-cause mortality. The analyses showed promising results for angina, but further study is needed.

Background/Overview

CAD occurs when the blood flow through one or more of the coronary arteries becomes inadequate, due to a combination of atherosclerotic plaques, clot formation, or perfusion of the myocardium. Typically, CAD is treated with medication, risk factor reduction, and possible surgery (CABG and/or PTCA). Although these techniques have been proven successful in many individuals with CAD, there are many people in the United States annually who suffer from incapacitating angina pain, but who are not suitable candidates for these surgical procedures, due to failed prior procedures, diffuse coronary artery disease, distal stenoses, or very small coronary arteries.

Both open and percutaneous TMR are techniques that attempt to improve blood flow to ischemic heart muscle via the creation of direct channels into the myocardium of the left ventricle. How TMR reduces angina is still not fully understood. The laser may stimulate new blood vessels to grow, called angiogenesis, and it may also destroy nerve fibers to the heart, making people unable to feel their chest pain. The open procedure is done via a thoracotomy (incision through the ribs to access the heart) on a beating heart without the use of cardiopulmonary bypass. The surgeon uses a laser to drill a series of holes from the epicardium into the heart's pumping chamber. In some individuals, TMR is combined with bypass surgery. Using a femoral arterial approach, percutaneous myocardial revascularization uses a fiberoptic catheter to create channels in the myocardium. In contrast to open TMR, where the channels extend from the epicardium to the endocardium, in a percutaneous approach the channels are created from the endocardium to the epicardial surface.

Definitions

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Angina pectoris: Chest pain that is typically severe and crushing. The individual experiences a feeling of pressure and suffocation just behind the breastbone (the sternum) caused by an inadequate supply of oxygen to the heart muscle.

Classes of angina:

- Class I: Ordinary physical activity does not cause angina
- Class II: Slight limitation of ordinary activity
- Class III: Marked limitation of ordinary physical activity
- Class IV: Inability to carry on physical activity without discomfort

Myocardial ischemia: Inadequate blood supply (circulation) to a part of the heart due to blockage of the vessels supplying blood to the area.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

- 33140 Transmyocardial laser revascularization, by thoracotomy; (separate procedure)
- 33141 Transmyocardial laser revascularization, by thoracotomy; performed at the time of other open cardiac procedure(s) [add-on]

ICD-10 Procedure

- 021L0Z5 Bypass left ventricle to coronary circulation, open approach
For the following codes when specified as TMR:
- 02QA0ZZ Repair heart, open approach
- 02QB0ZZ Repair right heart, open approach
- 02QC0ZZ Repair left heart, open approach

ICD-10 Diagnosis

- I20.0-I20.9 Angina pectoris
- I25.110-I25.119 Atherosclerotic heart disease of native coronary artery with angina pectoris
- I25.82 Chronic total occlusion of coronary artery
- I25.83 Coronary atherosclerosis due to lipid rich plaque
- I25.89 Other forms of chronic ischemic heart disease
- I25.9 Chronic ischemic heart disease, unspecified

When services are Investigational and Not Medically Necessary:

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For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

CPT

33999 Unlisted procedure, cardiac surgery [when specified as percutaneous transmyocardial revascularization]

ICD-10 Procedure

021L4Z5 Bypass left ventricle to coronary circulation, percutaneous endoscopic approach
For the following codes when specified as TMR:
02QA3ZZ-02QA4ZZ Repair heart, percutaneous/percutaneous endoscopic approach
02QB3ZZ-02QB4ZZ Repair right heart, percutaneous/percutaneous endoscopic approach
02QC3ZZ-02QC4ZZ Repair left heart, percutaneous/percutaneous endoscopic approach

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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2. Allen KB, Dowling RD, Angell WW, et al. Transmyocardial revascularization: 5-year follow-up of a prospective randomized multicenter trial. *Ann Thorac Surg.* 2004; 77(4):1228-1234.
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4. Allen GS. Mid-term results after thoracoscopic transmyocardial laser revascularization. *Ann Thorac Surg.* 2005; 80(2):553-558.
5. Horvath KA. Results of prospective randomized controlled trials of transmyocardial laser revascularization. *Heart Surg Forum.* 2002; 5(1):33-39; discussion 39-40.
6. Iwanski J, Knapp SM, Avery R, et al. Clinical outcomes meta-analysis: Measuring subendocardial perfusion and efficacy of transmyocardial laser revascularization with nuclear imaging. *J Cardiothorac Surg.* 2017; 12(1):37.
7. Leon MB, Kornowski R, Downey WE, et al. A blinded randomized placebo-controlled trial of percutaneous laser myocardial revascularization to improve angina symptoms in patients with severe coronary disease. *J Am Coll Cardiol.* 2005; 46(10):1812-1819.

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11. Saririan M, Eisenberg MJ. Myocardial laser revascularization for the treatment of end-stage coronary artery disease. *J Am Coll Cardiol.* 2003; 41(2):173-183.
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Government Agency, Medical Society, and Other Authoritative Publications:

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 - Transmyocardial Revascularization (TMR). NCD #20.6. Effective July 1, 1999.
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Websites for Additional Information

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	11/07/2019	MPTAC review. Updated References section.
Reviewed	11/08/2018	MPTAC review. Updated References section.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Revised	02/02/2017	MPTAC review. Removed abbreviations from Position Statement. Updated References and Index sections.
Reviewed	02/04/2016	MPTAC review. Updated Rationale. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Rationale.
Reviewed	02/13/2014	MPTAC review. Updated Rationale and References.
Reviewed	02/14/2013	MPTAC review. Updated Rationale, Index, and References.
Reviewed	02/16/2012	MPTAC review. Updated Rationale, References, Websites for Additional Information and Index.
	10/01/2011	Updated Coding section with 10/01/2011 ICD-9 changes.
Reviewed	02/17/2011	MPTAC review. References and Index updated.
Reviewed	02/25/2010	MPTAC review. References were updated.
Reviewed	02/26/2009	MPTAC review. Rationale, Background, Coding and References were updated.
	10/01/2008	Updated Coding section with 10/01/2008 ICD-9 changes.
Reviewed	02/21/2008	MPTAC review. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting. References were updated.
	10/01/2007	Updated Coding section with 10/01/2007 ICD-9 changes.
Reviewed	03/08/2007	MPTAC review. The Rationale and References sections were updated.
Reviewed	03/23/2006	MPTAC review. References were updated.

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11/22/2005 Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
 Revised 07/14/2005 MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/28/2005	SURG.00019	Transmyocardial Revascularization
WellPoint Health Networks, Inc.	04/28/2005	3.04.03	Transmyocardial Revascularization

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