



Clinical Review Criteria

Transmyocardial Laser Revascularization for Treatment of Severe Angina

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Transmyocardial Revascularization (TMR) (20.6)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Medical necessity review is not required for this service.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Transmyocardial revascularization (TMR) is a new treatment modality under evaluation in patients with severely symptomatic, diffuse coronary artery disease in whom the potential for medical or interventional management has been exhausted. Patients with end-stage coronary disease have a high morbidity and mortality due to cardiac events and other preexisting diseases.

TMR uses laser ablation to create transmural channels in ischemic myocardium by placing channels or holes in the oxygen-deprived heart muscle with the goal of restoring perfusion to the areas of the heart that are not being reached by diseased or clogged arteries. Initial clinical trials of TMR in patients with chronic intractable angina have shown promising results: more than two thirds of TMR-treated patients experience an average reduction in angina symptoms and improved exercise tolerance. The exact mechanism of action for TMR is unclear, but possible explanations for favorable outcomes include mediation of direct blood flow between the left ventricular cavity and ischemic myocardium, improved perfusion by angiogenesis, an anesthetic effect by nerve destruction, and a potential placebo effect.

In August 1998, the FDA fully approved CO₂ laser TMR for the sole therapy of patients with class III and IV angina. HCFA has also approved this therapy for Medicare patients as of 7/1/99. The Cardiology group would like to know whether TMR might be indicated for other GHC patients as well.

Medical Technology Assessment Committee (MTAC)

Transmyocardial Laser Revascularization 11/11/1998: MTAC REVIEW

Evidence Conclusion: The FDA approved the Heart Laser® manufactured by PLC Systems in August of 1998. Its approved indication is to treat patients with coronary artery disease who have chest pain (angina) that cannot be controlled by medication or effectively treated by Percutaneous Transluminal Balloon Angioplasty (PTCA) or other surgical methods.

The use of transmyocardial laser revascularization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/14/2000: MTAC REVIEW

Transmyocardial Laser Revascularization

Evidence Conclusion: TMR appears to relieve angina and may also improve exercise tolerance in patients with refractory ischemia who may not be candidates for other therapies. However, there are a number of unresolved issues from the literature, including: questionable validity of some of the RCTs, statistical significance versus clinical significance, ultimate patient group that would benefit, lack of standardization of perioperative management, potential for high rate of adverse events associated with the procedure, mechanism of action unclear, subjective outcome data. Given these uncertainties, the efficacy and safety of TMR cannot be fully determined from the evidence available so far. Larger randomized controlled trials with careful attention to patient selection and randomization, appropriate endpoints, and adverse effects (some of which are ongoing), may provide further information regarding the efficacy and safety of this procedure and the patient subgroup that is most likely to benefit from this treatment modality.

Articles: Articles were selected based on study type. There were five randomized controlled trials (RCTs) comparing TMR with “standard treatment” and several prospective studies. Evidence tables were created for 3 randomized controlled trials and are attached. Reviews, editorials, and comments were reviewed, but no evidence tables were created. Schofield et al. Transmyocardial laser revascularization in patients with refractory angina: a randomized controlled trial. *Lancet* 1999; 353:519-24. See [Evidence Table](#). Burkoff et al. Transmyocardial laser revascularization compared with continued medical therapy for treatment of refractory angina pectoris: a prospective randomized trial. *Lancet* 1999; 354:885-90. See [Evidence Table](#). March et al. Transmyocardial laser revascularization with the CO₂ laser: one-year results of a randomized controlled trial. *Seminars in Thoracic and Cardiovascular Surgery* 1999; 11(1):12-18. See [Evidence Table](#).

The use of transmyocardial laser revascularization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Non-Medicare – medical necessity review not required

Considered Medically Necessary when criteria in the applicable Medicare policy statements listed above are met:

CPT® Codes	Description
33140	Transmyocardial laser revascularization, by thoracotomy; (separate procedure)
33141	Transmyocardial laser revascularization, by thoracotomy; performed at the time of other open cardiac procedure(s) (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
11/11/1998	05/03/2011 ^{MDCRPC} , 08/02/2011 ^{MDCRPC} , 06/05/2012 ^{MDCRPC} , 04/02/2013 ^{MDCRPC} , 02/04/2014 ^{MPC} , 10/06/2015 ^{MPC} , 08/02/2016 ^{MPC} , 06/06/2017 ^{MPC} , 04/03/2018 ^{MPC} , 04/02/2019 ^{MPC} , 04/07/2020 ^{MPC} , 04/06/2021 ^{MPC}	05/03/2011

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description