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# Medical Policy Transmyocardial Revascularization

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Policy Number: 651

BCBSA Reference Number: 7.01.54 NCD/LCD: National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6)

#### **Related Policies**

None

### Policy Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Transmyocardial laser revascularization may be considered <u>MEDICALLY NECESSARY</u> 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 >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 <u>MEDICALLY NECESSARY</u> 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.

Transmyocardial laser revascularization is considered **INVESTIGATIONAL** for all other indications not meeting the above criteria.

Percutaneous transmyocardial laser revascularization is considered INVESTIGATIONAL.

## Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determinations (NCDs)

National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6)

**Note:** To review the specific NCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

## **Prior Authorization Information**

#### Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

#### Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.
Medicare HMO Blue <sup>sm</sup>	This procedure is performed in the inpatient setting.
Medicare PPO Blue <sup>SM</sup>	This procedure is performed in the inpatient setting.

## **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

#### **CPT Codes**

CPT codes	Code 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)

### **ICD-10 Diagnosis Codes**

ICD-10-CM Diagnosis	
codes:	Code Description
021L0Z5	Bypass Left Ventricle To Coronary Circulation, Open Approach

## Description

#### **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.<sup>1</sup>

#### 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 Transmyocardial Revascularization

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 (eg, 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.

#### Summary

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).

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, 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, 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. The 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 technology on health outcomes.

### **Policy History**

Date	Action
4/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
9/2019	Outpatient prior authorization information clarified to N/A. This service is primarily performed in an inpatient setting.
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statement(s) unchanged.
3/2018	New references added from BCBSA National medical policy. Background and summary clarified.
3/2017	New references added from BCBSA National medical policy.
10/2014	BCBSA National medical policy review. Investigational indications clarified. Coding information clarified. Effective 10/1/2014.
2/2014	Coding information clarified.
12/2013	New references from BCBSA National medical policy.
11/2013	Changed prior authorization information as prior authorization has always been required for this policy.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
2/2012	BCBSA National medical policy review. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
9/2010	BCBSA National medical policy review. Changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
4/2009	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
12/2008	BCBSA National medical policy review. No changes to policy statements.
4/2008	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
11/2007	BCBSA National medical policy review. No changes to policy statements.
4/2007	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.

### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

## References

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