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# Medical Policy **Transmyocardial Revascularization**

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Description

**Policy Number: 651** 

BCBSA Reference Number: 7.01.54 (For Plan internal use only)

# **Related Policies**

None

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

Transmyocardial laser revascularization may be considered **MEDICALLY NECESSARY** for individuals 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 MEDICALLY NECESSARY as an adjunct to coronary artery bypass grafting (CABG) in those individuals 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.

# **Prior Authorization Information**

#### Inpatient

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

#### Outpatient

Information Pertaining to All Policies

• 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. |

### 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 Procedure Code

| ICD-10-CM<br>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 as percutaneous TMR (PTMR). PTMR (also called percutaneous myocardial channeling) is a catheter-based system using holmium: yttrium-aluminum garnet 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

#### 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 transmyocardial revascularization (TMR), the evidence includes several randomized controlled trials (RCTs). Relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and 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 (LVEF) greater than 30%. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have coronary artery disease (CAD) and are undergoing coronary artery bypass graft (CABG) with documented areas of ischemic myocardium that cannot be surgically revascularized who receive TMR as adjunctive treatment, the evidence includes meta-analyses of RCTs. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, health status measures, quality of life, and treatment-related mortality and 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 an improvement in the net health outcome.

For individuals who have class III or IV angina refractory to medical treatment who receive percutaneous TMR (PTMR), the evidence includes a number of RCTs. Relevant outcomes are disease-specific survival, symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and 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 that the technology results in an improvement in the net health outcome.

| Date   | Action   |  |
|--------|--|--|
| 4/2024 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |  |
| 4/2023 | Annual policy review. Minor editorial refinements to policy statements; intent unchanged.        |  |
| 3/2022 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |  |
| 4/2021 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |  |

### **Policy History**

| 1/2021   | Medicare information removed. See MP #132 Medicare Advantage Management for   |
|----------|---|
|          | local coverage determination and national coverage determination reference.   |
| 4/2020   | Annual 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   | Annual policy review. Description, summary, and references updated. Policy statements unchanged.                                      |
| 3/2018   | Annual policy review. Description, summary, and references updated. Policy statements unchanged.                                      |
| 3/2017   | New references added from Annual policy review.   |
| 10/2014  | Annual policy review. New references added. Investigational indications clarified. Coding information clarified. Effective 10/1/2014. |
| 2/2014   | Coding information clarified.   |
| 12/2013  | Annual policy review. New references added.   |
| 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   | Annual policy review. No changes to policy statements.  |
| 4/2011   | Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.  |
| 9/2010   | Annual 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  | Annual policy review. No changes to policy statements.  |
| 4/2008   | Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.  |
| 11/2007  | Annual 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

- Laham RJ, Simons M. Transmyocardial laser revascularization for management of refractory angina. In: Aldea GS, Verrier E, Gersh BJ, ed. UpToDate. Waltham, MA: UpToDate Inc.; February 2023. https://www.uptodate.com/contents/transmyocardial-laser-revascularization-for-management-ofrefractory-angina. Accessed January 3, 2024.
- 2. Briones E, Lacalle JR, Marin I. Transmyocardial laser revascularization versus medical therapy for refractory angina. Cochrane Database Syst Rev. Jan 21 2009; (1): CD003712. PMID 19160223
- Briones E, Lacalle JR, Marin-Leon I, et al. Transmyocardial laser revascularization versus medical therapy for refractory angina. Cochrane Database Syst Rev. Feb 27 2015; 2015(2): CD003712. PMID 25721946

- Schofield PM, Sharples LD, Caine N, et al. Transmyocardial laser revascularisation in patients with refractory angina: a randomised controlled trial. Lancet. Feb 13 1999; 353(9152): 519-24. PMID 10028979
- Frazier OH, March RJ, Horvath KA. Transmyocardial revascularization with a carbon dioxide laser in patients with end-stage coronary artery disease. N Engl J Med. Sep 30 1999; 341(14): 1021-8. PMID 10502591
- Burkhoff D, Schmidt S, Schulman SP, et al. Transmyocardial laser revascularisation compared with continued medical therapy for treatment of refractory angina pectoris: a prospective randomised trial. ATLANTIC Investigators. Angina Treatments-Lasers and Normal Therapies in Comparison. Lancet. Sep 11 1999; 354(9182): 885-90. PMID 10489946
- Allen KB, Dowling RD, Fudge TL, et al. Comparison of transmyocardial revascularization with medical therapy in patients with refractory angina. N Engl J Med. Sep 30 1999; 341(14): 1029-36. PMID 10502592
- Aaberge L, Nordstrand K, Dragsund M, et al. Transmyocardial revascularization with CO2 laser in patients with refractory angina pectoris. Clinical results from the Norwegian randomized trial. J Am Coll Cardiol. Apr 2000; 35(5): 1170-7. PMID 10758957
- Jones JW, Schmidt SE, Richman BW, et al. Holmium:YAG laser transmyocardial revascularization relieves angina and improves functional status. Ann Thorac Surg. Jun 1999; 67(6): 1596-601; discussion 1601-2. PMID 10391261
- Peterson ED, Kaul P, Kaczmarek RG, et al. From controlled trials to clinical practice: monitoring transmyocardial revascularization use and outcomes. J Am Coll Cardiol. Nov 05 2003; 42(9): 1611-6. PMID 14607448
- 11. Saririan M, Eisenberg MJ. Myocardial laser revascularization for the treatment of end-stage coronary artery disease. J Am Coll Cardiol. Jan 15 2003; 41(2): 173-83. PMID 12535804
- Allen KB, Dowling RD, Angell WW, et al. Transmyocardial revascularization: 5-year follow-up of a prospective, randomized multicenter trial. Ann Thorac Surg. Apr 2004; 77(4): 1228-34. PMID 15063241
- Campbell F, Messina J, FitzGerald P, et al. Systematic review of the efficacy and safety of transmyocardial and percutaneous laser revascularisation for refractory angina pectoris. 2008 November http://www.nice.org.uk/guidance/ipg302/documents/systematic-review-of-the-efficacy-andsafety-of- transmyocardial-and-percutaneous-laser-revascularisation-for-refractory-angina-pectoris2. Accessed January 3, 2024.
- 14. Liao L, Sarria-Santamera A, Matchar DB, et al. Meta-analysis of survival and relief of angina pectoris after transmyocardial revascularization. Am J Cardiol. May 15 2005; 95(10): 1243-5. PMID 15878002
- 15. McGillion M, Cook A, Victor JC, et al. Effectiveness of percutaneous laser revascularization therapy for refractory angina. Vasc Health Risk Manag. Sep 07 2010; 6: 735-47. PMID 20859544
- 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. Nov 15 2005; 46(10): 1812-9. PMID 16286164
- 17. Oesterle SN, Sanborn TA, Ali N, et al. Percutaneous transmyocardial laser revascularisation for severe angina: the PACIFIC randomised trial. Potential Class Improvement From Intramyocardial Channels. Lancet. Nov 18 2000; 356(9243): 1705-10. PMID 11095257
- Stone GW, Teirstein PS, Rubenstein R, et al. A prospective, multicenter, randomized trial of percutaneous transmyocardial laser revascularization in patients with nonrecanalizable chronic total occlusions. J Am Coll Cardiol. May 15 2002; 39(10): 1581-7. PMID 12020483
- 19. Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. Dec 18 2012; 60(24): e44-e164. PMID 23182125
- 20. Patel MR, Calhoon JH, Dehmer GJ, et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease : A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography

and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. J Nucl Cardiol. Oct 2017; 24(5): 1759-1792. PMID 28608183

- Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. Aug 29 2023; 148(9): e9-e119. PMID 37471501
- 22. Hillis LD, Smith PK, Anderson JL, et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Developed in collaboration with the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. J Am Coll Cardiol. Dec 06 2011; 58(24): e123-210. PMID 22070836
- 23. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. Dec 06 2011; 58(24): e44-122. PMID 22070834
- Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. Jan 18 2022; 145(3): e18e114. PMID 34882435
- 25. National Institute for Health and Care Excellence. Transmyocardial laser revascularisation for refractory angina pectoris [IPG301]. 2009; https://www.nice.org.uk/guidance/ipg301. Accessed January 2, 2024.
- 26. National Institute for Health and Care Excellence. Percutaneous laser revascularisation for refractory angina pectoris [IPG302]. 2009; https://www.nice.org.uk/guidance/ipg302. Accessed January 3, 2024.
- Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6). 1999; https://www.cms.gov/medicare-coveragedatabase/details/ncd- details.aspx?NCDId=120&ncdver=1&bc=BAABAAAAAAAA. Accessed January 3, 2024.