

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>TRANSMYOCARDIAL REVASCULARIZATION</b>
<b>POLICY NUMBER</b>	<b>MP- 1.057</b>

<b>Effective Date:</b>	<b>10/1/2023</b>
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### I. POLICY

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 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 coronary artery bypass grafting 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 as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Percutaneous transmyocardial laser revascularization is **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

### II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

**FEP PPO-** Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

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### III. DESCRIPTION/BACKGROUND

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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).

#### **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.

#### **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 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 (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 demonstrated coronary artery atherosclerosis not amendable to direct coronary revascularization. In 1999, the Eclipse TMR 2000™ was approved by FDA through the premarket approval process for similar indications. Neither device is approved for use as an adjunct to coronary artery bypass graft. Use of either device for this purpose would be considered an off-label indication.

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PMA product code: MNO.

### IV. RATIONALE

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#### 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). 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 concerns 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 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 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.

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### V. DEFINITIONS

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**CLASS III ANGINA** refers to marked limitation of ordinary physical activity. Angina occurs on walking one to two blocks and climbing one flight of stairs in normal conditions at a normal pace.

**CLASS IV ANGINA** refers to inability to carry on physical activity without discomfort -angina symptoms may be present at rest.

**CORONARY ARTERY BYPASS SURGERY (CABG) IS THE SURGICAL ESTABLISHMENT OF A SHUNT THAT PERMITS BLOOD TO TRAVEL FROM THE AORTA OR INTERNAL MAMMARY ARTERY TO A BRANCH OF THE CORONARY ARTERY AT A POINT PAST AN OBSTRUCTION.**

**ISCHEMIA** refers to a temporary deficiency of blood flow to an organ or tissue.

**OFF- LABEL** refers to the use of a drug for a disease or condition other than the indication for which it was approved by the FDA.

**PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) IS A METHOD OF TREATING LOCALIZED CORONARY ARTERY NARROWING. A SPECIAL DOUBLE-LUMEN CATHETER IS DESIGNED SO THAT A CYLINDRICAL BALLOON SURROUNDS A PORTION OF IT. AFTER THE CATHETER IS INSERTED INTO THE ARTERY, INFLATION OF THE BALLOON DILATES THE NARROWED VESSEL.**

**REVASCULARIZATION** is the restoration of blood flow to a part.

**THORACOTOMY** refers to surgical incision of the chest wall.

### VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

### VII. DISCLAIMER

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*Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

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### VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Percutaneous transmymocardial laser revascularization is investigational; therefore, not covered:**

Procedure Codes							
33999							

**Covered when medically necessary:**

Procedure Codes							
33140	33141						

ICD-10-CM Diagnosis Code	Description
I20.0	Angina pectoris, unstable angina
I20.1	Angina pectoris with documented spasm
I20.2	Refractory angina pectoris
I20.81	Angina pectoris with coronary microvascular dysfunction
I20.89	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.112	Atherosclerotic heart disease of native coronary artery with refractory angina pectoris
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.89	Other forms of chronic ischemic heart disease

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1. Laham RJ, Simons M. Transmyocardial laser revascularization for management of refractory angina. In: Saperia GM, ed. UpToDate. Waltham, MA: UpToDate Inc.; 2023
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
3. 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; (2): CD003712. PMID 25721946
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
12. 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
13. 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



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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
16. 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
18. 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, Calhoun 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
21. 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
22. 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

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Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. Dec 06, 2011; 58(24): e44-122. PMID 22070834

23. 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): e18-e114. PMID 34882435
24. National Institute for Health and Care Excellence. Transmyocardial laser revascularisation for refractory angina pectoris [IPG301]. 2009
25. National Institute for Health and Care Excellence. Percutaneous laser revascularisation for refractory angina pectoris [IPG302]. 2009
26. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6). 1999
27. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.54, Transmyocardial Revascularization. March 2023

### X. POLICY HISTORY

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<b>MP 1.057</b>	<b>11/8/19 Consensus review.</b> No change to the policy statements. The word “open” was removed from the medically necessary policy statements. Background and references updated. Rationale revised.
	<b>8/16/2019 Consensus Review.</b> Policy statement unchanged. References updated.
	<b>11/06/2020 Consensus review.</b> No change to the policy statements. No references added.
	<b>3/26/2021 Consensus review.</b> No change to policy statement. Coding reviewed.
	<b>12/13/2021 Consensus review.</b> Updated FEP and references. No changes to coding.
	<b>03/28/2022 Consensus review.</b> No change to policy statement. Background updated. References added.
	<b>03/16/2023 Consensus review.</b> No change to policy statement. Background, Rationale and References updated. ICD10 codes I20.2, I20.9, I25.112, I25.118 added. I25.11 removed.
	<b>09/11/2023 Administrative update.</b> ICD10 code definitions revised due to new code. Added ICD10 codes I20.81 and I20.89. Removed ICD10 I20.8. Effective 10/1/2023

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