MEDICAL POLICY

POLICY TITLE	TRANSMYOCARDIAL REVASCULARIZATION
POLICY NUMBER	MP 1.057

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**7/1/2025**

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.

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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.

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: (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.

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.

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.

REVASCULARIZATION is the restoration of blood flow to a part.

THORACOTOMY refers to surgical incision of the chest wall.

VI. DISCLAIMER

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Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

VII. 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 transmyocardial 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

VIII. REFERENCES

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X. POLICY HISTORY

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MP 1.057	**11/08/2019 Consensus Review**. No change to the policy statements. The word "open" was removed from the medically necessary policy statements. Background and references updated. Rationale revised**.**
	08/16/2019 Consensus Review. Policy statement unchanged. References updated.
	11/06/2020 Consensus Review. No change to the policy statements. No references added.
	03/26/2021 Consensus Review. No change to policy statement. Coding reviewed.
	12/13/2021 Consensus Review. Updated FEP and references. No changes to coding.
	03/28/2022 Consensus Review. No change to policy statement. Background updated. References added.
	03/16/2023 Consensus Review. No change to policy statement. Background, Rationale and References updated. ICD10 codes I20.2, I20.9, I25.112, I25.118 added. I25.11 removed.
	09/11/2023 Administrative Update. ICD10 code definitions revised due to new code. Added ICD10 codes I20.81 and I20.89. Removed ICD10 I20.8. Effective 10/01/2023
	03/22/2024 Consensus Review. No change to policy statement. References added.
	02/20/2025 Consensus Review. No change to policy statement.
	06/09/2025 Administrative Update. Removing the Benefit Variations and updating the Disclaimer.

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