# MEDICAL POLICY

| POLICY TITLE | TRANSMYOCARDIAL REVASCULARIZATION |
|---|---|
| POLICY NUMBER | MP- 1.057 |

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| **Original Issue Date (Created):** | **2/25/2003** |
| **Most Recent Review Date (Revised):** | **8/19/2019** |
| **Effective Date:** | **10/1/2019** |



## I. POLICY

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Transmyocardial laser revascularization may be considered **medically necessary** for patients with class III or IV angina, **who are not candidates** for coronary bypass graft (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA) surgery who meet **ALL** of the following criteria:

- Presence of class III or IV angina and failed maximum 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; and
- No severe comorbid illness such as chronic obstructive pulmonary disease.

Transmyocardial laser revascularization may be considered **medically necessary** as an adjunct to coronary 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 as there is insufficient evidence to support a 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 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 BlueCross 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 MP-7.01.54, Transmyocardial Revascularization. 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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### 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 (CABG) who do not achieve complete revascularization.[1]

**TRANSMYOCARDIAL REVASCULARIZATION**TMR is performed under general anesthesia via a thoracotomy. 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. Various port access procedures are being evaluated to use TMR using novel robotic and thoracoscopic techniques.

### PERCUTANEOUS TMR

TMR can also be performed by the percutaneous route (PTMR). PTMR (also now being called percutaneous myocardial channeling or PMC) is a catheter-based system using Ho: 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, there are potential disadvantages to the PTMR approach. To minimize the possibility 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 U.S. Food and Drug Administration (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 RCTs. 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 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, 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. 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 the technology on health outcomes.

## 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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

## VII. DISCLAIMER

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*Capital BlueCross'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 BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## 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 transmyocardial laser revascularization is investigational; therefore, not covered:**

| CPT Codes ® | | | | | | | |
|---|---|---|---|---|---|---|---|
| 33999 | | | | | | | |



**Covered when medically necessary:**

| CPT Codes ® | | | | | | | |
|---|---|---|---|---|---|---|---|
| 33140 | 33141 | | | | | | |



| ICD-10-CM Diagnosis Code | Description |
|---|---|
| I20.0 | Angina pectoris, unstable angina |
| I20.1 | Angina pectoris with documented spasm |
| I20.8 | Other forms of angina pectoris |
| I25.10 | Atherosclerotic heart disease of native coronary artery without angina pectoris |
| I25.11 | Atherosclerotic heart disease of native coronary artery with 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 |
| I25.118 | Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris |

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| ICD-10-CM Diagnosis Code | Description |
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| I25.89 | Other forms of chronic ischemic heart disease |

## IX. REFERENCES

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***Other:***

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## X. POLICY HISTORY

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|---|---|
| **MP 1.057** | **CAC 10/28/02** |
| | **CAC 4/27/04** |
| | **CAC 6/28/05** |
| | **CAC 7/25/06** |
| | **CAC 7/31/07** |
| | **CAC 7/29/08** |
| | **CAC 7/28/09** Consensus Review |
| | **CAC 4/26/11** Adopt BCBSA. No changes to policy statements. |
| | **CAC 6/26/12** Consensus, no change to policy statements, references updated. |
| | **7/29/13** Admin coding review complete. |
| | **CAC 9/24/13** Consensus. No change to policy statements, references updated. Rationale section added. |
| | **CAC 9/30/14** Consensus. Policy statement added indicating open TMR is considered investigational for all other indications not meeting the medical necessity criteria. No changes to coding or configuration. Policy remains consensus. References and rationale sections updated. |
| | **CAC 9/29/15** Consensus review. No changes to the policy statements. Reference and rationale update. FEP variation added. Coding Reviewed |
| | **CAC 9/27/16** Consensus review. No changes to the policy statements. Rationale and Reference sections updated. Coding reviewed/updated. Variation reformatting completed. |
| | **CAC 11/28/17** Consensus review. No change to policy statements. Rationale and references updated. Coding reviewed. |
| | **11/8/19** 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**.** |
| | **8/16/2019** Consensus Review. Policy statement unchanged. References updated. |

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