BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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TRANSMYOCARDIAL REVASCULARIZATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Transmyocardial revascularization (TMR), also known as transmyocardial laser revascularization (TMLR), is a surgical technique that attempts to improve blood flow to ischemic heart muscle via the creation of direct channels from the left ventricle into the myocardium.

Open Transmyocardial Revascularization (TMR):
The open procedure is performed under general anesthesia via a thoracotomy. 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 to improve blood flow.

Percutaneous Transmyocardial Laser Revascularization (PTMR):
PTMR, also called percutaneous myocardial channeling (PMC) is performed by interventional cardiologists, who create myocardial channels by threading a laser-transmitting catheter to the endocardial surface inside the left ventricle. To minimize the possibility of cardiac tamponade, the myocardial channels created by PTMR are not as deep as those made by TMLR. In addition, positioning the laser under fluoroscopic guidance is less precise than the direct visual control of TMR. PTMR is being performed in Europe but there are currently no FDA approved devices approved for PTMR in the U.S.

TRANSMYOCARDIAL REVASCULARIZATION (cont.)

Criteria:

Transmyocardial laser revascularization will be reviewed by the medical director(s) and/or clinical advisor(s).

Open (Left Anterior Thoracotomy) Transmyocardial Laser Revascularization:

- Open transmyocardial laser revascularization for an individual with Class III or IV angina is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual is not a candidate for coronary artery bypass graft (CABG) or percutaneous transluminal coronary arterioplasty (PTCA)
  2. Angina is refractory to standard medical treatment (including drug therapy at the maximum tolerated or maximum safe dosage)
  3. Ejection fraction greater than 30%
  4. Documentation of reversible ischemia
  5. No evidence of recent myocardial infarction or unstable angina within the last 21 days
  6. No severe comorbid illness such as chronic obstructive pulmonary disease (COPD)

- Open transmyocardial laser revascularization as an adjunct to coronary artery bypass grafting (CABG) is considered ***medically necessary*** with documentation of areas of ischemic myocardium not amenable to surgical revascularization.

Percutaneous Transmyocardial Laser Revascularization (PTLR):

- Percutaneous transmyocardial laser revascularization is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.

TRANSMYOCARDIAL REVASCULARIZATION (cont.)

Resources:

1. 7.01.54 BCBS Association Medical Policy Reference Manual. Transmyocardial Revascularization. Re-issue date 08/08/2013, issue date 05/30/1997.

2. BCBS Association Technology Assessment Program. TMR as an Adjunct to CABG Surgery for the Treatment of Coronary Artery Disease. 05/2001;16(1)

3. Bridges CR, Horvath KA, Nugent WC, et al. Transmyocardial Revascularization Guideline The Society of Thoracic Surgeons Practice Guideline Series Transmyocardial Laser Revascularization. 2003

4. Bridges CR, Horvath KA, Nugent WC, et al. The Society of Thoracic Surgeons practice guideline series: transmyocardial laser revascularization. *Ann Thorac Surg.* 2004 Apr;77(4):1494-1502

5. Peterson ED, Kaul P, Kaczmarek RG, et al. From controlled trials to clinical practice: monitoring transmyocardial revascularization use and outcomes. *J Am Coll Cardiol.* 2003 Nov 5;42(9):1611-1616

6. Saririan M, Eisenberg MJ. Myocardial laser revascularization for the treatment of end-stage coronary artery disease. J Am Coll Cardiol. 2003 Jan 15;41(2):173-183

7. Yang SS, Li WM, Yin LL, et al. [Chronic effects of percutaneous transmyocardial laser revascularization in patients with refractory angina]. Zhonghua Xin Xue Guan Bing Za Zhi. 2007 Jan;35(1):51-54