Geisinger Health Plan Policies and Procedure Manual

Policy: MP062

Section: Medical Benefit Policy

Subject: Transmyocardial Laser Revascularization

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Transmyocardial Laser Revascularization

II. Purpose/Objective:
To provide a policy of coverage regarding Transmyocardial Laser Revascularization

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

ADDITIONAL DEFINITIONS:

Coronary artery bypass graft (CABG)

A procedure in which a healthy blood vessel is harvested from another part of the body and grafted into the coronary artery allowing revascularization, resulting in blood-flow through the graft supplying the heart with adequate blood and oxygen.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

A procedure used to dilate a coronary artery. A catheter is inserted through the skin and threaded through a major blood vessel into the blocked area of the coronary artery. The catheter is surrounded by a deflated balloon. At the area of blockage, the balloon is inflated, flattening the blockage against the artery wall and enlarging the inside of the vessel.

Transmyocardial

Across or through the heart muscle

DESCRIPTION:

Transmyocardial laser revascularization (TMLR) is a procedure that attempts to improve blood flow to ischemic heart muscle through the creation of channels from the left ventricle to the myocardium. This procedure is used as a late or last resort for relief of symptoms of severe refractory angina in members who have myocardial ischemia but are not candidates for other types of revascularization procedures such as coronary artery bypass surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA).

INDICATIONS FOR COVERAGE: All Must Be Met

- Class III or IV angina (New York Heart Association or Canadian Cardiovascular Society Angina Classification) intractable despite maximal medical therapy (see tables 1 and 2); and
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) is contraindicated, or the angina symptoms are caused by an area of the heart not amenable to surgical therapies; and
- Ejection fraction of 30% or greater; and
- Evidence of reversible ischemic/hibernating myocardium
- Patient is stable with no evidence of
    - Recent MI or unstable angina within the last 21 days; or
    - Decompensated congestive heart failure; or
    - Uncontrolled ventricular or supraventricular tachyarrhythmias; or
    - Severe comorbid illness such as but not limited to, chronic obstructive pulmonary disease

Table 1

The New York Heart Association (NYHA) functional classification of angina pectoris:

Class I.	Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
Class II.	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
Class III.	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV.	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Table 2

Canadian Cardiovascular Society functional classification

Canadian Cardiovascular Society–functional classification severity of unstable angina

Class I

Usual physical activity, eg walking or climbing stairs, does not cause angina; angina is evoked by strenuous and/or rapid work or recreation

Class II

Slight limitation of ordinary activities, eg after walking 2 blocks, climbing one flight of steps, under normal circumstances, after meals, in the cold, wind, in the morning, or when under emotional stress

Class III

Marked limitation of ordinary activities, eg walking 1-2 blocks or climbing stairs under normal circumstances

Class IV

Inability to carry out any physical activity without discomfort–angina may be present at rest.

Circulation 1976, 54:522; JAMA, 1999; 281:1258-1260

CONTRAINDICATIONS:

- Ejection fraction less than 30%
- Peripheral vascular disease preventing intra-aorta balloon pump placement for:
  - Low ejection fraction
  - Unstable angina
- Severe comorbid illness such as but not limited to, chronic obstructive pulmonary disease
- Major fixed defects on thallium/PET
- Ongoing myocardial injury

EXCLUSIONS:

Applications listed under Contraindications

There is insufficient evidence in the peer-reviewed published medical literature to establish the use of TMLR plus cell therapy with autologous bone marrow cells for the treatment of ischemic heart disease. Therefore, the Plan does **NOT** provide coverage for this service because it is considered to be **experimental, investigational or unproven.**

There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of percutaneous transmyocardial laser revascularization (PTLR). Therefore, the Plan does **NOT** provide coverage for this service because it is considered to be **experimental, investigational or unproven.**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Transmyocardial Laser Revascularization

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

33140 Transmyocardial laser revascularization, by thoracotomy (separate procedure)
33141 performed at the same time of other open cardiac procedures

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Technology Evaluation Center, TEC Evaluation. ""Transmyocardial Revascularization for the Treatment of Coronary Artery Disease", Feb. 1999; 13(23):1-28.

Geisinger Technology Assessment Committee, "Transmyocardial Revascularization", Jan. 13, 1999

Technology Evaluation Center, TEC Evaluation," TMR as an Adjunct to CABG Surgery for the Treatment of Coronary Artery Disease", May 2001; 16(1):1-26.

Schill S, Waetzig B, et.al., "Transmyocardial Laser Revascularization (TMLR) as a Therapeutic Procedure and a Stand-by Option in Patients with End Stage Coronary Artery Disease", *Circulation* 96(8S) Suppl:564-I – 565I, 21 Oct 1997.

Landolfo CK, Landolfo KP, Hughes GC, et. al., "Intermediate – Term Clinical Outcome Following Transmyocardial Laser Revascularization in Patients With Refractory Angina Pectoris", *Circulation*, 100(19) Suppl:II-128 – II-133, Nov 9, 1999.

Dowling RD, Petracek MR, Selinger SL, Allen KB, "Transmyocardial Revascularization in Patients with Refractory, Unstable Angina", *Circulation*, 98(19S) Suppl: 73II-75II, Nov 10, 1998.

Coughlin MK,"Comparison of Transmyocardial Revascularization with Medical Therapy in Patients with Refractory Angina" *AORN Journal*, 73(2):513, 515 Feb 2001.

ECRI, HTAIS Technology Assessment Report. Transmyocardial Laser Revascularization (TMR)/ Percutaneous Myocardial Laser Revascularization (PMR) for Treatment of Refractory Angina. Jan. 2004.

Winifred S. Hayes, Hayes Inc. Online. Transmyocardial Laser Revascularization. Aug. 2002. Update 7/16/04.

Bridges CR, Horvath KA, Nugent WC, Shahian DM, Haan CK, Shemin RJ, Allen KB, Edwards FH; Society of Thoracic Surgeons. The Society of Thoracic Surgeons practice guideline series: transmyocardial laser revascularization. Ann Thorac Surg. 2004 Apr; 77(4):1494-502.

Campeau L. Letter: Grading of angina pectoris. Circulation. 1976 Sep. 54(3):522-3

Gibbons RJ, Abrams J, Chatterjee K, Daley J, Deedwania PC, Douglas JS, Ferguson TBJr., Fihn SD, Fraker TD Jr., Gardin JM, O'Rourke RA, Pasternak RC,Williams SV. ACC/AHA 2002 guideline update for the management of patients with chronic stable angina: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines (Committee toUpdate the 1999 Guidelines for the Management of Patients with Chronic Stable Angina). 2002.
Accessed on March 8, 2006 at: http://www.acc.org/clinical/guidelines/stable/stable_clean.pdf

Dallan LA, Gowdak LH, Lisboa LA, et al. Cell therapy plus transmyocardial laser revascularization: A proposed alternative procedure for refractory angina. Rev Bras Cir Cardiovasc. 2008; 23(1):46-52.

Horvath KA. Transmyocardial laser revascularization. J Card Surg. 2008; 23(3):266-276.

Gowdak LH, Schettert IT, Rochitte CE, Rienzo M, Lisboa LA, Dallan LA, César LA, Krieger JE, Ramires JA, de Oliveira SA. Transmyocardial laser revascularization plus cell therapy for refractory angina. Int J Cardiol. 2008 Jul 4; 127(2):295-7. Epub 2007 Jul 31.

Up to Date. Transmyocardial laser revascularization for management of refractory angina. 2017.

Bockeria OL, Petrosyan AD, Shvartz VA, et al. Long-term results of isolated transmyocardial laser revascularization in combination with the intramyocardial autologous bone marrow stem cells injection. Lasers Med Sci. 2020;35(5):1111-1117.

Centers for Medicare & Medicaid Services. NCD 20.6 Transmyocardial Revascularization (TMR)

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. Journal of the American College of Cardiology, 2022: 79(2):e21-e129

This policy will be revised as necessary and reviewed no less than annually.

Devised: 08/98

Revised: 12/99; 02/02 (format); 03/03 (prior auth change), 3/04 definition; 3/05 (NYHA criteria replaced CCS); 3/06 (updated criteria); 3/10 (exclusion added); 4/12 (updated criteria); 4/15; 3/22 (Revise Language)

Reviewed: 3/07, 3/08, 3/09, 4/11, 4/13, 4/14, 4/16, 3/17, 3/18, 3/19, 3/20, 3/21, 3/23, 3/24

CMS UM Oversight Committee Approval: 12/23, 5/24