

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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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.

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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

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.