

Geisinger Health Plan Policies and Procedure Manual

Policy: MP060

Section: Medical Benefit Policy

Subject: Lung Volume Reduction Surgery

Applicable Lines of Business

| Commercial | Χ | CHIP | X |
|------------|---|------|---|
| Medicare | Χ | ACA | X |
| Medicaid | Χ | | |

I. Policy: Lung Volume Reduction Surgery

II. Purpose/Objective:

To provide a policy of coverage regarding Lung Volume Reduction Surgery

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;
- 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

DESCRIPTION:

Lung volume reduction surgery is a surgical treatment for severe emphysema. The surgical intent of lung volume reduction is to reduce airway obstruction by improving lung elastic recoil and by providing more effective diaphragmatic function by reducing lung hyperinflation. Lung volume reduction surgery is performed by excision of the affected lung tissue through an open thoracotomy or by video-assisted thoracoscopy.

The placement of small self-expanding 1-way valves into airways is a minimally invasive approach currently under investigation as an alternative to open LVRS. The implantable valves are deployed in diseased bronchial segments using a flexible fiber-optic bronchoscope inserted through the mouth or nose. The valves are designed to prevent incoming airflow from reaching over-inflated regions of the lung while permitting trapped gas to escape. In addition to isolating non-functional areas of the lungs, the valves have the potential to reduce hypoxemia and hypercarbia by directing airflow to areas where gas exchange is less impaired.

INDICATIONS:

REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION

Emphysema when **all** of the following criteria are met:

CRITERIA FOR ELIGIBILITY:

- > All surgeries must be performed at a CMS approved Center of Excellence
- Member has severe predominantly upper lobe emphysema; OR
- Member has severe non-upper lobe emphysema with low base-line exercise capacity (defined as below 25 watts for women and below 40 watts for men);

and

Satisfies all of the criteria outlined below:

| Assessment | Criteria | | |
|--------------------------------|--|--|--|
| | Consistent with emphysema | | |
| History /Physical Exam | BMI less than or equal to 31.1 kg/m2 (men) or less than or equal to 32.3 kg/m2 (women) | | |
| | Stable with less than or equal to 20 mg prednisone (or equivalent) per day | | |
| Radiographic | Evidence of bilateral emphysema with a High Resolution Tomography Scan. | | |
| Pulmonary Function (pre-rehab) | Forced expiratory volume in one second (FEV1) less than or equal to 45% predicted (15% or greater predicted if age 70 years or more) | | |
| | Total lung capacity equal to or greater than 100% predicted post bronchodilator | | |
| | Residual volume 150% or greater predicted post bronchodilator | | |
| Arterial Blood Gas (pre-rehab) | PCO2 60mmHg or less (55mmHg or less if 1 mile above sea level) | | |
| | PO2 45 mmHg or greater on room air (30 mmHg or greater if 1 mile above sea level) | | |
| Cardiac | Approval for surgery by a cardiologist if any of the following are present: • Unstable angina | | |
| | LVEF cannot be estimated from echocardiogram LVEF 45% or less | | |

| Assessment | Criteria |
|------------|--|
| | Dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction Arrhythmia (more than 5 PVC's /minute; cardiac rhythm other than sinus; PVC on EKG at rest) |
| Surgical | Approved for surgery by a pulmonary physician, thoracic surgeon and anesthesiologist post-rehabilitation |
| Exercise | Post rehabilitation 6 minute walk of 140 meters or more; able to complete 3 minutes of unloaded pedaling in exercise tolerance test (pre and post rehab) |
| Smoking | Plasma cotinine level of 13.7 ng/mL or less (or arterial carboxyhemoglobin of 2.5% or less if using nicotine products) |
| | Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery |

National Coverage Determination (NCD) for LUNG VOLUME REDUCTION Surgery (REDUCTION Pneumoplasty) (240.1)

NOTE: Effective March 2, 2006 For member enrolled in the Gold product only, Medicare will consider LVRS reasonable and necessary only when services are performed on or after November 17, 2005 and performed at a facility that is:

- Certified by the Joint Commission on Accreditation of Healthcare Organizations (joint Commission) under the LVRS Disease Specific Care Certification Program; OR
- Approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial; OR
- Medicare-certified for lung or heart-lung transplantation.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/LVRS/list.asp

ENDOBRONCHIAL VALVE LUNG VOLUME REDUCTION Please see MP370

EXCLUSIONS:

The Plan does not cover Laser bullectomy for emphysema or bronchoscopic lung volume reduction procedures (e.g., biologic lung volume reduction, bronchopulmonary fenestration) because they are considered **experimental**, **investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this procedure on health outcomes when compared to established tests or technologies.

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.

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.

CODING ASSOCIATED WITH LUNG VOLUME REDUCTION SURGERY:

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

CPT Codes:

- 32124 thoracotomy, with open intrapleural pneumoysis
- 32141 thorocotomy, with excision plication of bullae, with or without any pleural procedure
- 32655 thorocoscopy, surgical, with excision plication of bullae, including any pleural procedure
- 32672 Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed
- 32999 unlisted procedure, lungs and pleura
- 32491 Excision-plication of emplysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthroacic approach with or without and pleural procedure
- 94726 Plethysmography for determination of lung volumes and, when performed, airway resistance
- 94727 Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes
- G0302 Pre-op service LVRS complete
- G0303 Pre-op service 10-15 dos
- G0304 Pre-op service 1-9 dos
- G0305 Post op service LVRS

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

LINE OF BUSINESS:

Eligibility and contract specific benefit 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: 4/96

Revised: 1/98, 6/02, 6/03(definition, criteria, reference); 7/05 (update criteria); 11/06(Update Criteria); 12/10 (exclusion added), 12/11(updated criteria), 4/23 (remove exclusion, add referral to MP370)

Reviewed: 11/07, 11/08, 11/09, 12/12, 12/13, 12/14; 12/15, 12/16, 11/17, 11/18, 10/19, 10/20, 10/21, 10/22, 4/24

CMS UM Oversight Committee Approval: 12/23, 7/24

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/qhp-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 endors ement by Geisinger Health

| Plan, Geisinger Quality Options, Inc. described under this medical policy. | and Geisinger Indemnity Insurance C | ompany regarding the medical service | , medical device or medical lab test |
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