Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP 370

Section: Medical Policy

Subject: Endobronchial Valve

Applicable Lines of Business

Commercial	**X**	**CHIP**	**n/a**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Endobronchial Valve

II. Purpose/Objective: To provide a policy of coverage regarding Endobronchial Valve

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.

DESCRIPTION:
Endobronchial Valves are implantable bronchial valves used for the bronchoscopic treatment of adults with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

INDICATIONS:

1. Endobronchial valve placement with an FDA approved device (e.g., Zephyr® or Spiration® Valve System) may be considered medically necessary for the treatment of severe emphysema when the member's dyspnea symptoms are poorly controlled, and activities of daily living are markedly restricted despite maximal medical management and completion of pulmonary rehabilitation and when **ALL** of the following criteria are met:
   - Forced expiratory volume (FEV1) is less than 45% of predicted value
   - Residual volume is greater is 180% predicted or greater
   - Total lung capacity is greater than or equal to 100% predicted;
   - 6-minute walking distance ≥100m
   - Targeted lobe shows little to no collateral ventilation (CV);
   - Abstinence from smoking of any kind for 4 consecutive months prior to initial evaluation, and throughout the evaluation for the procedure; AND
   - Body mass index (BMI) greater than 15 kg/m2 and less than 35 kg/m2.

2. Endobronchial valves may be considered medically necessary for the treatment of prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery.

EXCLUSIONS:
The use of endobronchial valves is considered investigational and therefore **NOT COVERED** when the member has any of the following:

- does not meet the coverage criteria outlined in this policy
- has previously undergone ipsilateral lung volume reductive surgery or lung/lobar transplant.
- has evidence of active pulmonary infection.
- has known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium) or silicone, unless being treated by an allergist.
- has evidence of large bullae encompassing greater than 30% of either lung**.**

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:
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.***

31647 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe
31648 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe
31649 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe
31651 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe

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:

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Buttery SC, Banya W, Bilancia R, et al. Lung volume reduction surgery versus endobronchial valves: a randomised controlled trial. Eur Respir J. Apr 2023; 61(4).

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

Devised: 3/23

Revised:

Reviewed: 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/ghp-clinical-policies