CLINICAL MEDICAL POLICY	
Policy Name:	Bronchial Valves
Policy Number:	MP-109-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2023; 11/01/2022; 12/17/2022; 11/23/2020; 12/09/2019
Effective Date:	12/01/2023; 12/01/2022; 01/17/2022; 12/21/2020; 12/09/2019
Next Annual Review:	09/2024
Revision Date:	09/20/2023; 09/21/2022; 09/15/2021; 09/16/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

Policy History

Date	Activity
12/01/2023	Provider Effective date
10/19/2023	PARP Approval
09/20/2023	QI/UM Committee review
09/20/2023	Annual Review: No changes to experimental/investigational stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2022	Provider Effective date
10/19/2022	PARP Approval
09/21/2022	QI/UM Committee review
09/21/2022	Annual Review: No changes to clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
01/17/2022	Provider effective date
11/30/2021	PARP Approval
09/15/2021	QI/UM Committee review
09/15/2021	Annual Review: No changes to clinical criteria. Added TAG documentation information. Updated Summary of Literature, and Reference sections.
12/21/2020	Provider effective date
10/22/2020	PARP approval
09/16/2020	QI/UM Committee review

09/16/2020	Annual Review: Added definition for bronchoscopic lung volume reduction; no change in coverage position; removed Contraindications as service is not covered; updated Summary of Literature and Reference sections.
12/09/2019	Provider effective date
10/21/2019	PARP approval
09/18/2019	QI/UM Committee review
09/18/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage under the Company's Medicaid products bronchial valves in all situations. The use of bronchial valves are considered investigational and therefore, not medically necessary.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Emphysema - A severe form of chronic obstructive pulmonary disease which there is an abnormal permanent enlargement of the distal airspace and in the terminal bronchioles, along with loss of elasticity of alveolar walls along with the supporting structures of the alveoli.

Bronchoscopic Lung Volume Reduction (BLVR) - Nonsurgical physical intervention targeting diseased lung tissue to provide symptom relief of chronic obstructive pulmonary disease (COPD). There are two types of one-way valves used for BLVR: Endobronchial Valves (EBV) and Intrabronchial Valves (IBV).

Procedures

1. The use of bronchial valves is considered experimental/investigational due to insufficient evidence in all situations, including, but not limited to, for the treatment of prolonged air leaks and treatment in patients with chronic obstructive pulmonary disease (COPD) or emphysema.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for the placement of bronchial valves is inpatient.

Governing Bodies Approval

There are several bronchial valve systems approved by the FDA:

- The Umbrella Implantable IntraBronchial Valve (IBV) Valve System was approved by the FDA under the Humanitarian Device Exemption (HDE) on October 24, 2008. The device was approved to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or lung volume reduction surgery.
- The Spiration Valve System was approved by the FDA on a Humanitarian Device Exemption on August 17, 2015 and December 3, 2018. This one-way Endobronchial valves is indicated for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation.
- Zephyr Endobronchial Valve System was approved by the FDA on June 29, 2018. This implantable system consists of a one-way silicone duckbill valve attached to a nickel-titanium self-expanding retainer that is covered with a silicone membrane. It is indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

CMS
The Centers for Medicare and Medicaid Services (CMS) has no current National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) for bronchial valves identified at the time of this medical policy review.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of July 2013, the TAG workgroup has assigned the bronchial valve system an Option # 4, specifically for CPT codes 31647, 31648, 31649, & 31651.

Summary of Literature

Chronic obstructive pulmonary disease, or COPD, refers to a group of diseases that cause airflow blockage and breathing-related problems. It includes emphysema and chronic bronchitis. Symptoms of COPD may include frequent coughing or wheezing, excess phlegm, mucus, or sputum production, shortness of breath, and/or trouble taking a deep breath. Chronic lower respiratory disease, primarily COPD, was the fourth leading cause of death in the United States in 2018. Almost 15.7 million Americans (6.4%) reported that they have been diagnosed with COPD. More than 50% of adults with low pulmonary function were not aware that they had COPD, so the actual number may be higher. There are several options utilized in the treatment of emphysema depending upon the severity of the disease. These options can include medications, smoking cessation, pulmonary rehabilitation, oxygen therapy, and lung volume reduction surgery and lung transplantation (CDC, 2021).

COPD is a chronic and progressive disease with no curative treatment approach except lung transplantation, which may be considered in a minority of select patients with advanced COPD. The main goal of therapy is to stop the progression of the disease and reduce disease-induced mortality. According to the international COPD guidelines by the Global initiative for chronic Obstructive Lung Disease (GOLD), smoking cessation, disease-adapted exercise, and pulmonary rehabilitation as well as influenza and pneumococcal vaccinations are the most important therapeutic strategies. Pharmacological therapy of COPD includes bronchodilatation (β2-agonists and anticholinergic agents), topical corticosteroids, and oral phosphodiesterase inhibitors depending on the severity of dyspnea, bronchoconstriction, and the frequency of exacerbations. Long-term oxygen therapy may be recommended in patients with chronic respiratory failure. Ventilatory support is indicated in patients with significant hypercapnia and related clinical symptoms (Eberhardt, Gompelmann, Herth, Schuhmann, 2015).

The GOLD recommendations for endobronchial valves are currently listed as an ‘A’ for use in select patients with advanced emphysema as bronchoscopic interventions reduce end-expiratory lung volume and improve exercise tolerance, health status and lung function at 6-12 months following treatment. A comparison of treatment benefits and complications associated with endobronchial valve placement compared with LVRS show comparable benefits with endobronchial valve treatment with fewer complications. However, additional data is needed to define the optimal bronchoscopic lung volume technique to produce bronchoscopic lung volume reduction in patients who lack fissure integrity, or exhibit collateral ventilation, and to refine the procedure to reduce complications and improve longer term clinical outcomes (GOLD, 2023).

The current evidence on the safety and efficacy of EBV insertion is adequate in quantity and quality to support the use of the procedure provided that standard arrangements are in place for clinical governance, consent and audit. Patient selection should be done by a multidisciplinary team experienced in managing emphysema, which should typically include a chest physician, a radiologist, a thoracic surgeon and a respiratory nurse. Patients selected for treatment should have previously had pulmonary rehabilitation. The procedure should only be done to occlude volumes of the lung where there is no collateral ventilation, by clinicians with specific training in doing the procedure (NICE, 2017).

While there are studies that documented positive outcomes that were statistically significant, there is lack of consistency on the certainty of clinical significance. The safety of the procedure has not been confirmed as noted with the wide range of adverse events stemming for the use of bronchial valves in the clinical trials.

Hayes, Inc

- Comparative Effectiveness Review of Bronchoscopically Placed Coils or Valves For Lung Emphysema: A Review Of Reviews:
    - **B Rating** - For use of endobronchial valves (EBV) in adult patients with severe heterogeneous lung emphysema without collateral ventilation.
    - **D2 Rating** - Endobronchial coils for use in adult patients with homogenous or heterogeneous lung emphysema.
    - **D2 Rating** - Intrabronchial valves for use in adult patients with heterogeneous lung emphysema.
    - Current evidence indicates that compared with medical management, EBV consistently confers clinical benefits, and that the intrabronchial valves and endobronchial coils may confer some health benefits. All forms of bronchoscopic lung volume reduction (BLVR) were associated with a greater incidence of adverse events than medical management, although there appears to be no increase in mortality associated with BLVR. However, follow-up intervals were generally short (< 1 year) and studies may not be adequately powered to detect differences in mortality between groups.

Coding Requirements

Non-covered Procedure Codes

These procedure codes will not be reimbursed without Medical Director approval.

CPT Code	Description
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 (List separately in addition to code for primary procedure)
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 (List separately in addition to code for primary procedure[s])

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: OPS # 7/2013-008. Option #4. Accessed on August 17, 2022.

Hayes, Inc. Comparative effectiveness review of bronchoscopically placed coils or valves for lung emphysema: a review of reviews. February 25, 2019. Reviewed January 18, 2022. Accessed on August 23, 2023.

National Institute for Health and Care Excellence. Endobronchial valve insertion to reduce lung volume in emphysema. December 20, 2017. Accessed on August 17, 2022.

Global Initiative for Chronic Obstructive Lung Disease, Inc (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2023 report. Accessed on August 17, 2023.

Centers for Disease Control and Prevention (CDC). Basics About COPD. June 9, 2021. Accessed on August 17, 2022.

Eberhardt R, Gompelmann D, Herth FJ, Schuhmann M. Endoscopic bronchial valve treatment: patient selection and special considerations. Int J Chron Obstruct Pulmon Dis. October 8, 2015. Accessed on August 17, 2022.