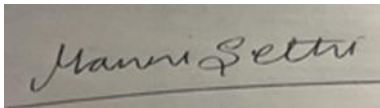


**Prior Authorization Review Panel  
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.  
Policies submitted without this form will not be considered for review.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                 |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
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| Plan: AmeriHealth Caritas Pennsylvania & Keystone First                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Submission Date: 4/1/2026                                                                                                       |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
| Policy Number: CCP.1420                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Effective Date: 7/1/2019<br>Revision Date: 3/1/2026                                                                             |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
| Policy Name: Endobronchial Valve Placement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                 |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
| <div style="display: flex; justify-content: space-between;"><div>Type of Submission:</div><div>Type of Policy:</div></div> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;"><input type="checkbox"/> New Policy</td><td style="width: 50%; padding: 5px;"><input checked="" type="checkbox"/> Prior Authorization Policy</td></tr><tr><td style="padding: 5px;"><input checked="" type="checkbox"/> Revised Policy*</td><td style="padding: 5px;"><input type="checkbox"/> Base Policy</td></tr><tr><td style="padding: 5px;"><input type="checkbox"/> Annual Review- no revisions</td><td style="padding: 5px;"><input type="checkbox"/> Experimental/Investigational Policy</td></tr><tr><td style="padding: 5px;"></td><td style="padding: 5px;"><input type="checkbox"/> Statewide PDL</td></tr><tr><td style="padding: 5px;"></td><td style="padding: 5px;"><input type="checkbox"/> Other:</td></tr></table> |                                                                                                                                 | <input type="checkbox"/> New Policy | <input checked="" type="checkbox"/> Prior Authorization Policy | <input checked="" type="checkbox"/> Revised Policy* | <input type="checkbox"/> Base Policy | <input type="checkbox"/> Annual Review- no revisions | <input type="checkbox"/> Experimental/Investigational Policy |  | <input type="checkbox"/> Statewide PDL |  | <input type="checkbox"/> Other: |
| <input type="checkbox"/> New Policy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input checked="" type="checkbox"/> Prior Authorization Policy                                                                  |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
| <input checked="" type="checkbox"/> Revised Policy*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/> Base Policy                                                                                            |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
| <input type="checkbox"/> Annual Review- no revisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <input type="checkbox"/> Experimental/Investigational Policy                                                                    |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/> Statewide PDL                                                                                          |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
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| <p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any clarifying information for the policy below:</p> <p>Reactivated in 2026 to address a gap in InterQual.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                 |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |
| Name of Authorized Individual (Please type or print):<br><br>Manni Sethi, MD, MBA, CHCQM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Signature of Authorized Individual:<br><br> |                                     |                                                                |                                                     |                                      |                                                      |                                                              |  |                                        |  |                                 |



# Endobronchial Valve Placement

Clinical Policy ID: CCP.1420

Recent review date: 3/2026

Next review date: 7/2027

Policy contains: chronic obstructive pulmonary disease; emphysema; endobronchial valve; lung volume reduction

*Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.*

## Coverage policy

Endobronchial valve placement is clinically proven and, therefore, may be medically necessary for treatment of hyperinflation in adult members with severe emphysema (defined as  $\geq 50\%$  low attenuation score at -910 Hounsfield units or  $\geq 20\%$  at -950 Hounsfield units) adjacent to fissures that are at least 80% intact (Global Initiative for Chronic Obstructive Lung Disease, 2025; Wahidi, 2025).

### Limitations

Contraindications to endobronchial valve systems include (U.S. Food and Drug Administration, 2018a, 2018b):

- Inability to undergo bronchoscopic procedures.
- Presence of active pulmonary infection.
- Known or suspected allergies to Nitinol (a nickel-titanium alloy), its constituent metals (nickel or titanium), or silicone.
- Active smoking.

Endobronchial valve placement is not recommended for members with evidence of decompensated heart failure, severe pulmonary hypertension, predominant paraseptal emphysema, giant bullae, prior ipsilateral lobectomy or pleurodesis, or abnormalities that require follow-up imaging (e.g., indeterminate lung nodules) (Wahidi, 2025).

### Alternative covered services

- Guideline-directed medical therapy.
- Lung transplants.
- Lung volume reduction surgery.

- Bullectomy.

## Background

Chronic obstructive pulmonary disease is a term used for a group of progressive lung diseases for which there is no cure. In 2023, chronic obstructive pulmonary disease was the fifth leading cause of death in the United States and incurred annual medical costs of \$24 billion among adults age 45 and older. The most common types are emphysema and chronic bronchitis (Weeks, 2025).

Emphysema is a pathological diagnosis that affects the airways distal to the terminal bronchiole. It is characterized by permanent enlargement or destruction of these lung air spaces and a loss of elasticity in the lung parenchyma. This damage leads to hyperinflation of the lungs, which impedes diaphragmatic movement and impairs breathing mechanics and gas exchange. The most common cause of emphysema is prolonged exposure to smoke or harmful environmental factors (Lee, 2024; Pahal, 2025).

Diagnosis of emphysema includes assessment of smoking history, environmental factors, occupational risk, and family history during the history and physical. As the disease worsens, chronic shortness of breath, cough, and sputum production progress. Pulmonary function tests are the standard for diagnosing the disease and its severity. Treatment involves bronchodilators and anti-inflammatory medication. Supportive treatment includes oxygen therapy/ventilatory support, pulmonary rehabilitation, and palliative care. Lung volume reduction surgery, endoscopic lung volume reduction, bullectomy, and lung transplant may also be considered (Pahal, 2025).

Endobronchial valve placement is a minimally invasive and reversible procedure that involves placing one-way valves within the airways of the lungs that are most damaged. The valves allow trapped air to exit during expiration and prevents air from entering during inspiration, thereby reducing volume in the occluded lobe. Potential improvements in patient health status may be measured using forced expiratory volume in one second, the six-minute walk test, and quality of life measures (American Lung Association, 2025).

Two endobronchial valve systems have been approved for use in the United States for treating adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little or no collateral ventilation. They are the Zephyr Endobronchial Valve System (Pulmonx Corporation, Redwood City, California) and the Spiration Valve System (Gyrus Acmi, Inc., Redmond, Washington) (U.S. Food and Drug Administration, 2018c, 2018d).

Endobronchial valve placement is contraindicated in individuals with known allergies to nickel, titanium, or silicone; in active smokers or anyone with active pulmonary infection; in anyone unable to undergo bronchoscopic procedures; and in the presence of large bullae. In addition, endobronchial valve therapy may not be possible in cases of prior lung surgery, pleural diseases, cancer, or severe heart disease (U.S. Food and Drug Administration, 2018a, 2018b).

## Findings

Evidence from large, randomized trials supports the safety and efficacy of endobronchial valve placement to improve pulmonary function, functional status, and dyspnea in persons with advanced, hyperinflated emphysema. Guidelines typically include patient selection criteria largely derived from clinical trial inclusion criteria and expert opinion. The greatest benefits have been observed in adult patients with heterogeneous emphysema and no evidence of collateral ventilation, but those with homogeneous emphysema may achieve benefit as well. Candidates should have intact fissures to reduce the risk of post-procedural pneumothorax.

### Guidelines

The Global Initiative for Chronic Obstructive Lung Disease (2025) states that endobronchial valve placement may be a therapeutic option for patients with heterogeneous or homogeneous emphysema with significant hyperinflation refractory to optimized medical care. The choice of lung volume reduction procedure will depend on several factors, such as the extent and pattern of emphysema and presence of interlobar collateral ventilation. Quantitative analysis using computed tomography is commonly used to assess the extent, location, and fissure integrity of emphysema. In the case of endobronchial valve placement, the presence of an intact fissure on high-resolution computed tomography or bronchoscopic balloon occlusion testing between the treated and non-treated lobe is needed for procedural success.

Another international expert consensus group expanded on clinical guidance for assessing candidacy for bronchial lung volume reduction (Wahidi, 2025). The group discussed patient factors, radiological findings, and physiological testing considerations that may affect candidacy, bearing in mind that the threshold at which any specific parameter should be considered an absolute contraindication is controversial or undefined. The group's primary rationale for caution in the presence of significantly abnormal physiological testing is the potential for a reduced magnitude of benefit and the risk of sudden-onset complications like periprocedural pneumothorax.

The group recommended targeting lobes with extensive emphysema ( $\geq 50\%$  low attenuation score at  $-910$  Hounsfield units or  $\geq 20\%$  at  $-950$  Hounsfield units) and lobes adjacent to fissures that are at least  $80\%$  intact. These thresholds were used in randomized trials. In addition, the group recommended against endobronchial valve placement for patients with evidence of decompensated heart failure, severe pulmonary hypertension, predominantly paraseptal emphysema or giant bullae, prior ipsilateral lobectomy or pleurodesis, recent active infection, or abnormalities such as indeterminate lung nodules (Wahidi, 2025).

### Evidence review

Systematic reviews and meta-analyses of randomized trials have examined the safety and efficacy of endobronchial valve placement compared to optimized medical therapy and other lung volume reduction procedures. In several randomized, controlled clinical trials, endobronchial valve placement mitigates hyperinflation and achieves clinically relevant improvements in dyspnea, pulmonary function, exercise capacity, and quality of life 12 months after valve implantation. The greatest benefits have been observed in patients with heterogeneous emphysema and no evidence of collateral ventilation. However, the risk of exacerbations and pneumothorax in the first six months is higher, long-term outcomes are unclear, and data on procedure-related mortality are limited. Careful patient selection on the basis of fissure status and emphysema pattern is critical to achieving procedural success.

Díaz-Miravalls (2025) compared the efficacy and safety of endobronchial valve placement to optimized standard medical therapy from nine randomized controlled trials ( $n = 1,352$ ) with at least six months of follow-up data. Outcomes were reported as weighted mean difference with  $95\%$  confidence intervals. Participants with endobronchial valves achieved a significantly greater improvement in forced expiratory volume in one second ( $12.73\%$ ,  $4.73$  to  $18$ ,  $P < .001$ ), and a significant reduction in residual volume. They also showed effective deflation of hyperinflated lungs ( $-413.35$  milliliters,  $-591.59$  to  $-235.11$ ,  $P < .001$ ), significantly improved quality of life on the Saint George Respiratory Questionnaire ( $-7.16$  points,  $-10.39$  to  $-3.93$ ,  $P < .001$ ), improvement in exercise capacity as measured by the six-minute walk test ( $35.37$  meters,  $19.12$  to  $51.63$ ,  $P < .001$ ), and reduced dyspnea severity ( $-0.35$  grades,  $-0.52$  to  $-0.17$ ,  $P < .001$ ). There was high heterogeneity observed in these primary outcome measures — suggesting variability in study populations, procedural protocols, and follow-up durations — but sensitivity analyses confirmed the generalizability of the observed benefits across diverse settings.

For secondary outcomes, results were reported as an odds ratio with  $95\%$  confidence intervals. Endobronchial valves were associated with higher odds of experiencing moderate-to-severe exacerbations ( $1.71$ ,  $1.05$  to  $2.78$ ,  $P = .032$ ), severe exacerbations ( $1.96$ ,  $1.25$  to  $3.08$ ,  $P = .003$ ), and pneumothorax ( $12.31$ ,  $4.81$  to  $31.58$ ,  $P < .001$ ).

.001). Mortality rates did not differ significantly between groups (1.78, 0.69 to 4.61,  $P = .236$ ). Low-to-moderate heterogeneity was observed for the secondary outcome measures (Díaz-Miravalls, 2025).

Ter Haar's (2025) review of more than 80 prospective and retrospective studies found that both surgical and bronchoscopic lung volume reduction procedures may have positive extrapulmonary effects in patients with severe emphysema and lung hyperinflation. Positive effects in inflammatory and oxidative stress markers, anxiety, depression, and bone mineral density were reported, but the effects on cognition, sleep, and peripheral muscle function were inconclusive. These findings require confirmation from higher-quality studies.

Endobronchial valve placement compared favorably to other lung volume reduction procedures. In two network meta-analyses by Bo (2025) and Yamamoto (2025), compared to standard medical care, both lung volume reduction surgery and some bronchoscopic techniques — such as endobronchial valves and endobronchial coils — significantly enhanced lung function, exercise capacity, and quality of life, but they were also associated with significantly higher adverse event rates. Lung volume reduction surgery offers the greatest efficacy benefits but carries the highest risks, whereas bronchoscopic options provide safe and effective alternatives in terms of symptoms and functional improvement, but also carry a greater risk of pneumothorax. However, no lung volume reduction therapy significantly reduced mortality.

In 2026, we reactivated the policy per a field request. Based on new guideline recommendations and results of secondary analyses, we updated the coverage criteria to medically necessary.

## References

On 2/2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were: “lung volume reduction,” “emphysema,” “endobronchial valve,” and “chronic obstructive pulmonary disease.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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## Policy updates

Initial review date: 6/2019 and clinical policy effective date: 7/2019

6/2020: Policy references updated.

6/2021: Policy references updated.

6/2022: Policy retired.

3/2026: Policy reactivated. Coverage changed to medically necessary.

## Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1420. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

| Code   | 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                                                                        |
| +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]) |
| 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)                                                                                    |

