Lung Volume Reduction Surgery

Description of Procedure or Service

Emphysema is an anatomically defined condition characterized by destruction and enlargement of lung alveoli. It is one of the conditions considered as a chronic obstructive pulmonary disease along with chronic bronchitis and small airways disease. The pathogenesis of emphysema is primarily related to cigarette smoking leading to inflammation and recruitment of immune cells to the terminal air spaces of the lung. The resultant extracellular matrix proteolysis damages the lung. Destruction of the gas exchanging air spaces and ineffective repair of the extracellular matrix results in airspace enlargement. Emphysema can be characterized into distinct pathologic subtypes. Centriacinar emphysema is most frequently associated with cigarette smoking, is usually most prominent in the upper lobes and superior segments of the lower lobes and is focal. Panacinar emphysema is characterized by abnormally large air spaces evenly distributed across acini in the lower lobes. It is associated with a1-antitrypsin deficiency. Key pulmonary function parameters are the volume of the first forced expiratory effort (FEV1) and the total volume of air exhaled during the spirometry (forced vital capacity [FVC]). Airflow obstruction related to chronic obstructive pulmonary disease is characterized by reduced ratio of FEV1/FVC and reduction in FEV1, correlates with long-term mortality risk.

Lung volume reduction surgery (LVRS) is proposed as a treatment option for patients with severe emphysema who have failed optimal medical management. The procedure involves the excision of diseased lung tissue and aims to reduce symptoms and improve quality of life.

Lung volume reduction is a surgical treatment for patients with severe emphysema involving the excision of peripheral emphysematous lung tissue, generally from both upper lobes. The precise mechanism of clinical improvement for patients undergoing lung reduction surgery has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of diseased lung. In addition to changes in chest wall and respiratory mechanics, the surgery is purported to correct ventilation perfusion mismatch and improve right ventricular filling.

Complications from the surgical procedure include death, reintubation, arrhythmias, mechanical ventilation for more than two days, pneumonia, wound infection, and persistent air leak.

Research on LVRS has focused on defining the sub-group of patients most likely to benefit from the procedure. Potential benefits of the procedure e.g., improvement in functional capacity and quality of life must be weighed against the potential risk of the procedure e.g., risk of postoperative mortality.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for lung volume reduction surgery when it is medically necessary because the medical criteria and guidelines shown below have been met.
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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Lung Volume Reduction Surgery is covered

Lung volume reduction surgery as a treatment for emphysema may be considered medically necessary in patients with emphysema who meet ALL of the following criteria:

- Predominantly upper lobe emphysema with hyperinflation and heterogeneity
- Forced expiratory volume in one second (FEV-1): 1) for patients who are younger than 70 years of age, the FEV-1 must be no more than 45% of the predicted value; 2) for patients who are 70 years of age or older, the FEV-1 must be no more than 45% of the [redacted value and greater than or equal to 15% of the predicted value.]
- Marked restriction in activities of daily living despite maximal medical therapy
- Age younger than 75 years
- Acceptable nutrition status, i.e., 70-130% of ideal body weight
- Ability to participate in a vigorous pulmonary rehabilitation program
- No coexisting major medical problems that would significantly increase operative risk.
- Willingness to undertake risk of morbidity and mortality associated with LVRS
- Abstinence from cigarette smoking for at least 4 months

When Lung Volume Reduction Surgery is not covered

Lung volume reduction surgery is considered investigational when the criteria listed above have not been met.

BCBSNC does not cover investigational services.

Policy Guidelines

For individuals who have upper-lobe emphysema who receive LVRS, the evidence includes randomized controlled trials (RCTs) and systemic reviews of the trials. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality. Findings from the National Emphysema Treatment Trial (NETT), a multicenter RCT, suggest that LVRS is effective at reducing mortality and improving quality of life in select patients with severe emphysema. In subgroup analysis, LVRS offered a survival advantage only in patients not considered high risk who had predominately upper-lobe emphysema and low initial exercise capacity. Patients with upper-lobe emphysema, regardless of initial exercise capacity, experienced significant improvement in exercise capacity and quality of life after LVRS. Other, smaller RCTs have generally had similar findings, though they have tended to be underpowered for some outcomes and did not stratify by distribution of
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emphysema. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have non-upper-lobe emphysema who receive LVRS, the evidence includes subgroup analysis of a large RCT. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality. In the subgroup analysis of NETT, LVRS offered a survival advantage only in patients who had predominately upper-lobe emphysema. For the subgroup with predominately non-upper-lobe emphysema, NETT did not find significant mortality advantages or symptom improvement with LVRS. Although NETT had positive findings for the study population as a whole, given the surgical risks, additional data are needed to confirm the net health outcome in patients with non-upper-lobe emphysema. The evidence is insufficient to determine the effects of the technology on health outcomes.

The following additional criteria, also from the NETT trial, may provide further information in determining whether a patient is a candidate for lung volume reduction surgery:

- Arterial partial pressure of oxygen (PaO2) on room air greater than or equal to 45 mm Hg (greater than or equal to 30 mm Hg at elevations of 5,000 feet or higher)
- Arterial partial pressure of carbon dioxide (PaCO2) on room air less than or equal to 60 mm Hg (less than or equal to 55 mm Hg at elevations of 5,000 feet or higher)
- Post-rehabilitation 6-minute walk of at least 140 m, and able to complete 3 min. unloaded pedaling in exercise tolerance test

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 32491, G0302, G0303, G0304, G0305.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

TEC Bulletin - 11/95

Health Technology Assessment; Lung-Volume Reduction Surgery for End-Stage Chronic Obstructive pulmonary Disease by the U.S. Department of Health and Human Services, 9/96

Technology News - 12/96


TEC assessment Volume 14, number 1. Issued May 1999


Medical Policy Advisory Group - 12/2/1999

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Specialty Matched Consultant Advisory Panel review 3/2012


Specialty Matched Consultant Advisory Panel 3/2018


Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>4/96</td>
<td>Original policy issued</td>
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<tr>
<td>3/97</td>
<td>Policy changed to investigational</td>
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<tr>
<td>7/97</td>
<td>Removed code G0061 and added CPT 32491. Added Health Technology Assessment by the U.S. Department of Health and Human Services.</td>
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<tr>
<td>8/98</td>
<td>Reaffirm</td>
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7/99   Reformatted, Medical Term Definitions added.

12/99  Reaffirmed, Medical Policy Advisory Group

3/01   System change.


4/04   Billing/Coding section updated for consistency.

4/7/05  Policy status changed to: "Active policy, no longer scheduled for routine literature review." Codes G0302, G0303, G0304, G0305 added to Billing/Coding section. SUR6450, Lung shaving, Lung contouring, and Reduction Pneumoplasty added as key words. References added.

6/22/10 Policy Number(s) removed (amw)

3/30/12 Specialty Matched Consultant Panel review 3/21/2012. Converting active archive policy back to active policy. Updated the policy for consistency with BCBSA. Extensive revisions to Description and Policy Guidelines sections. Added the following updated information to "When Covered criteria section: Predominantly upper lobe emphysema with hyperinflation and heterogeneity; Forced expiratory volume in one second (FEV-1): 1) for patients who are younger than 70 years of age, the FEV must be no more than 45% of the predicted value; 2) for patients who are 70 years of age or older, the FEV-1 must be no more than 45 % of the predicted value; Marked restriction in activities of daily living despite maximal medical therapy; Age younger than 75 years; Acceptable nutrition status, i.e., 70-130% of ideal body weight; Ability to participate in a vigorous pulmonary rehabilitation program; No coexisting major medical problems that would significantly increase operative risk; Willingness to undertake risk of morbidity and mortality associated with LVRS; Abstinence from cigarette smoking for at least 4 months. (lpr)

8/7/12 Reference updated. No change in policy statement. (lpr)

4/16/13 Specialty Matched Consultant Advisory panel review meeting 3/20/13. Reference updated. No change to policy statement. (lpr)

8/13/13 Reference updated. No change to policy statement. (lpr)

7/29/14 Reference updated. Specialty matched consultant advisory panel review meeting 4/30/14. No change to policy statement. (lpr)

4/28/15 Specialty matched consultant advisory panel review 3/25/2015. No change to policy statement. (lpr)

7/28/15 Reference added. No change to policy statement. (lpr)

4/29/16 Updated Description section. Specialty Matched Consultant Advisory Panel review 3/30/2016. No change to policy statement. (lpr)
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7/26/16   Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)

4/28/17   Specialty Matched Consultant Advisory Panel review 3/29/2017. No change to policy statement. (lpr)

7/28/17   Updated Description section. Reference added. No change to policy statement. (lpr)

4/13/18   Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (lpr)

7/27/18   Reference added. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.