Lung Volume Reduction Surgery for Severe Emphysema
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00080
Original Effective Date: 08/26/2002
Archived Date: 09/17/2008

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Note: Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider lung volume reduction surgery (LVRS) as a treatment for emphysema to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility for lung volume reduction surgery as a treatment for emphysema will be considered when all of the following criteria are met:
- Predominantly upper lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)
- Forced expiratory volume (FEV-1) between 20% and 35% of predicted
- 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

When Services are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers LVRS in all other patients to be investigational.*

Background/Overview
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 LVRS 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...
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mismatch and improve right ventricular filling. VRS is palliative not curative. The procedure is designed to relieve dyspnea and improve functional capacity and quality of life. Patients continue to have severe emphysema, and most patients will show further progression of their disease over time.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
FDA regulation is not required for surgical procedures.

Rationale/Source
The 2003 TEC Assessment focused on the final results of the National Emphysema Treatment Trial (NETT). This trial reported the results of all 1,218 patients who underwent randomization. The primary outcomes included total, 30-day, and 90-day mortality and maximal exercise capacity. Secondary outcomes included pulmonary function, the distance walked in six minutes, and the results on a self-administered questionnaire about health-related quality of life and a general quality of life questionnaire. Only 371 patients were followed up for a total of 24 months. The following results were reported:

<table>
<thead>
<tr>
<th></th>
<th>90-day mortality (%)</th>
<th>Total mortality (no death/total)</th>
<th>Improvement in Exercise Capacity at 24 mos. (%) (2)</th>
<th>Improvement in Quality of Life at 24 mos. (%) (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical Treatment</td>
<td>Surgical Treatment</td>
<td>Medical Treatment</td>
<td>Surgical Treatment</td>
</tr>
<tr>
<td>All Patients</td>
<td>1.3</td>
<td>7.9</td>
<td>160 / 610</td>
<td>157 / 608</td>
</tr>
<tr>
<td>High Risk Patients (1)</td>
<td>28</td>
<td>0</td>
<td>30 / 70</td>
<td>42 / 70</td>
</tr>
<tr>
<td>Upper lobe Emphysema, low exercise capacity</td>
<td>3.3</td>
<td>2.9</td>
<td>51 / 151</td>
<td>26 / 139</td>
</tr>
<tr>
<td>Upper lobe Emphysema, high exercise capacity</td>
<td>0.9</td>
<td>2.9</td>
<td>39 / 213</td>
<td>34 / 206</td>
</tr>
<tr>
<td>Non-upper lobe Emphysema, low exercise capacity</td>
<td>0</td>
<td>8.3</td>
<td>28 / 84</td>
<td>26 / 65</td>
</tr>
<tr>
<td>Non-upper lobe Emphysema, high exercise capacity</td>
<td>0.9</td>
<td>10.1</td>
<td>27 / 109</td>
<td>14 / 111</td>
</tr>
</tbody>
</table>
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(1) High risk is defined as those with a forced expiratory volume in one second that was 20% or less of the predicted value and either homogeneous emphysema on computed tomography or a carbon monoxide diffusion capacity that was 20% or less of the predicted value.

(2) Improvement in exercise capacity in patients followed up for 24 months after randomization was defined as an increase in the maximal workload of more than 10 W from the patient’s post-rehabilitation baseline value.

(3) Improvement in health-related quality of life in patients followed up for 24 months after randomization was defined as a decrease in the score on the St George’s Respiratory Questionnaire of more than eight points (on a 100-point scale) from the patient’s post-rehabilitation baseline score.

The following observations can be drawn from the above data:

- The 90-day mortality for the surgery group (7.9%) is significantly higher than the medical therapy group (1.3%).
- The poor outcome of those considered at high risk reported in the initial publication of this trial was confirmed in this subsequent report.
- There was no significant difference in overall mortality despite a higher early mortality rate in the surgery group. Even when excluding those patients considered to be at high risk, there was no difference in overall mortality among non-high-risk patients.
- Among patients with predominantly upper lobe emphysema and low exercise capacity, mortality was lower in the surgery group than in the medical therapy group. In contrast, among those with predominantly non-upper lobe emphysema and high exercise capacity, mortality was higher in the surgery group.
- A significantly greater percentage of patients in the surgery group reported improvement in exercise capacity at all time periods, i.e., at six, 12, and 24 months.
- Patients in the surgery group were significantly more likely to have improvements in general and health-related quality of life compared to the medical group.

Based on the above, the authors offer the following conclusions:

- Overall, LVRS increases the chance of improved exercise capacity but does not confer a survival advantage over medical therapy; the functional benefits of LVRS come at the price of increased short-term mortality and morbidity.
- There is a survival advantage for patients with both predominantly upper lobe emphysema and low baseline exercise capacity. This survival advantage appears to be due to the very high mortality and marked progressive functional limitation of those treated medically.
- Patients considered at high risk and those with non-upper lobe emphysema and high baseline exercise capacity are poor candidates for LVRS.
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The TEC Assessment offered the following observations and conclusions:

The scientific evidence was sufficient to permit conclusions, and in a subgroup analysis, a mortality benefit was shown for LVRS in patients with predominantly upper lobe emphysema and low exercise capacity.

2004 Update
A literature search for the period of 2003 through October 2004 did not identify any additional published articles that would prompt reconsideration of the policy statement. Therefore, the policy statement remains unchanged. With the completion of the large multicenter randomized NETT study, it is unlikely that further controlled trials will be undertaken.

References

Coding
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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>HCPCS</td>
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<td>ICD-9 Diagnosis</td>
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<tr>
<td>ICD-9 Procedure</td>
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Policy History
Original Effective Date: 08/26/2002
08/15/2002 Medical Policy Committee review
08/26/2002 Managed Care Advisory Council approval
08/31/2002 Medical Director review
09/21/2004 Medical Policy Committee review. Format revision. No substance change to policy.
09/27/2004 Managed Care Advisory Council approval
08/03/2005 Medical Director review
08/16/2005 Medical Policy Committee review. Coverage eligibility statement unchanged.
08/24/2005 Managed Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/06/2006 Medical Director review
09/20/2006 Medical Policy Committee approval. No changes to policy guidelines.
09/05/2007 Medical Director review
09/19/2007 Medical Policy Committee approval. No change to coverage eligibility.
09/09/2008 Medical Director review
09/17/2008 Medical Policy Committee approval. Archived policy.
Next Scheduled Review Date: Archived Medical Policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is investigational will be based on a consideration of the following:
A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);
   2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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