Endobronchial Valves

Policy Number: 7.01.128    Last Review: 4/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for endobronchial valves. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Endobronchial valves are considered investigational as a treatment of prolonged air leaks.

Endobronchial valves are considered investigational as a treatment for patients with COPD or emphysema.

Considerations
Only one endobronchial valve device has approval from the U.S. Food and Drug Administration (FDA) through the Humanitarian Device Exemption (HDE) process for use in prolonged pulmonary air leaks.

Description of Procedure or Service
Endobronchial valves are synthetic devices that are deployed with bronchoscopy into ventilatory airways of the lung for the purpose of controlling airflow. They have been investigated for use in patients who have prolonged broncho-pleural air leaks, as well as an alternative to lung volume reduction surgery (LVRS) in patients with lobar hyperinflation from severe emphysema.

Background
Proper lung functioning is dependent upon a separation between the air-containing parts of the lung and the small vacuum-containing space around the lung called the pleural space. When air leaks into the pleural space, the lung is unable to inflate, resulting in hypoventilation and hypoxemia; this condition is known as a pneumothorax. A pneumothorax can result from a variety of processes including trauma, high airway pressures induced during mechanical ventilation, lung surgery, and rupture of lung blebs or bullae, which may be congenital or a result of chronic obstructive pulmonary disease (COPD).

Although an air leak from the lung into the pleural space may seal spontaneously, it often requires intervention. Techniques currently employed to attempt air leak closure include the following:
- Inserting a chest tube (tube thoracostomy) and employing a water seal or one-way valve to evacuate air collected in the pleural space and prevent it from reaccumulating,
- Lowering airway pressures by adjusting the mechanical ventilator,
- Using autologous blood patches,
- Performing a thoracotomy with mechanical or chemical pleurodesis.

An endobronchial valve is a device that permits one-way air movement. During inhalation the valve is closed preventing air flow to the diseased area of the lung. The valve opens during exhalation to allow
air to escape from the diseased area of the lung. When used to treat persistent air leak from the lung into the pleural space, the endobronchial valve theoretically permits less air flow across the diseased portion of the lung during inhalation, aiding in air leak closure. The valve may be placed, and subsequently removed, by bronchoscopy.

Endobronchial valves have also been investigated for use in severe emphysematous COPD. In emphysematous COPD, peripheral lung tissue may form bullae. These diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflate, compressing relatively normal lung tissue. They also may rupture, causing a pneumothorax. Use of an endobronchial valve is thought to prevent hyperinflation of these bullae.

Consideration for the use of endobronchial valves in COPD is based on the improvement observed in patients who have undergone lung volume reduction surgery (LVRS). LVRS involves excision of peripheral emphysematous lung tissue, generally from the upper lobes. The precise mechanism of clinical improvement for patients undergoing lung volume reduction has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of diseased lung. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative. Endobronchial valves have been investigated as a non-surgical alternative to LVRS.

**Regulatory Status**

In October 2008, the IBV® Valve System (Spiration, Inc, Redmond, WA) was approved by the U.S. Food and Drug Administration (FDA) under the Humanitarian Device Exemption (HDE) for use in controlling 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 (LVRS). An air leak present on postoperative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. IBV Valve System use is limited to 6 weeks per prolonged air leak.

In December 2008, the Zephyr Endobronchial Valve (formerly Emphasys, now Pulmonx, Redwood City, CA) was considered by the Anesthesiology and Respiratory Therapy Device Panel for use as a permanent implant intended to improve forced air expiratory volume in 1 second (FEV1) and 6-minute walk test distance in patients with severe, heterogeneous emphysema who have received optimal medical management. The panel declined to recommend the device for FDA approval. As of January 2013, the Zephyr Endobronchial Valve has not been cleared by the FDA.

**Rationale**

**Literature Review**

This policy was created with a search of the MEDLINE database through October 2010. It was updated regularly; the most recent search of the MEDLINE database was for the period January 16, 2013 through January 7, 2014. A summary of the key literature is as follows:

**Treatment of air leaks**

No randomized controlled trials (RCTs) or comparative observational studies were identified. Only case series and case report data are available. The largest case series, published in 2009, reported on 40 patients treated at 17 sites in the United States and Europe; 6 of the patients had been included in previously published case reports. (1) Zephyr (Emphasys, now Pulmonx) endobronchial valves were used. Data were abstracted retrospectively from medical records. No specific eligibility criteria were reported, and patients did not need to demonstrate that they were refractory to other treatments. All patients in the series had prolonged pulmonary air leak (mean duration of 119 days, median of 20
Twenty-five patients had continuous air leaks, 14 had expiratory air leaks, and 1 was unidentified. The most common comorbidities were cancer and COPD. Prior to the procedure, 39 of the 40 patients had at least 1 chest tube. Five patients had other treatments eg, blood patch before valve placement. The mean number of valves placed per patient was 2.9 (standard deviation [SD]=1.9) overall. After valve placement, 19 patients (47.5%) had complete resolution of acute air leak, 18 (45%) had a reduction in air leak, 2 (5%) had no change, and data were not available for 1 patient. The mean time from valve placement to chest tube removal was 21 days, and the median time was 7.5 days (data from 2 patients were not available). Eight patients had the valves removed after the air leak ceased; in 32 patients, the clinician chose to leave the valves in place. Six patients experienced adverse effects related to valve placement including valve expectoration, moderate oxygen desaturation, initial malpositioning of a valve, pneumonia and *Staphylococcus aureus* colonization. The length of follow-up was highly variable, ranging from 5 to 1109 days. At last follow-up, 16 patients were reported to have died; none of the deaths were attributed to the valve or the valve implantation procedure.

The next largest case series published to date was 2013 study by Firlinger et al in Austria. The study included 16 patients with persistent continuous air leak ie, having an intrathoracic chest tube for more than 7 days, despite conservative and/or surgical therapy. Endobronchial valves were placed in 13 of 16 patients; the source of the air leak could not be identified in the other 3 individuals. FDA-approved Spiration IBV valves were used in 9 patients, and Zephyr valves were used in the other 3 patients. Ten of 13 (77%) patients were considered responders, defined as patients in whom successful chest tube removal occurred without the need for further intervention. Spiration IBV valves were used in 6 of 10 responders and all 3 nonresponders.

In addition, a 2011 case series reported on 9 patients with pulmonary air leaks evaluated for treatment with Spiration IBV valves. Target airways could not be identified in 2 patients, and valves were placed in 7 patients. One of the 7 had 2 procedures due to development of an additional air leak after the first one was treated and resolved. The median duration of air leaks in the 7 patients before valve placement was 4 weeks (range, 2 weeks to 5 months). Complete air leak cessation occurred in 6 of 8 procedures after a mean duration of 5.2 days. The other 2 procedures resulted in reduction of air leak. There were no operative or postoperative complications attributed to the bronchial valves. The valves were removed in 5 of the 7 patients at a mean of 37 days after placement (range, 14 to 55 days). Valves were not removed in one patient who entered hospice care and in the patient who underwent 2 procedures because the patient declined removal.

Section summary: The only available data on endobronchial valves for treating persistent air leaks are uncontrolled trials with small numbers of heterogenous patients. Data on FDA-approved endobronchial valve device are particularly limited; Spiration valves were successfully placed in 7 patients in 1 case series and 9 patients in another. This evidence is not adequate to determine the impact of this technology on the net health outcome, nor does it provide any evidence on comparisons with alternatives.

**Treatment of emphysema**

The published literature consists of one RCT and several case series.

**Randomized controlled trial**

The RCT, called the Endobronchial Valve for Emphysema Palliation Trial (VENT) was an industry-sponsored multicenter multinational study. The primary study results were reported separately for the sites in the United States and those in Europe. Results from the 31 U.S. sites were reported in 2010, and results from the 23 sites in Europe were reported in 2012. Key eligibility criteria were: diagnosis of heterogenous emphysema, FEV1 of 15%-45% of the predicted value, total lung capacity of more than 100% of the predicted value, residual volume of more than 150% of the predicted value, and postrehabilitation 6-minute walk distance of at least 140 meters. Prior to randomization, all patients received 6-8 weeks of pulmonary rehabilitation and medical management that was optimized at the discretion of the treating physician, using guidelines from the Global Initiative for Chronic Obstructive
Lung Disease. Patients who remained eligible for the study after undergoing the preliminary treatment program were randomized to receive therapy using the Zephyr endobronchial valve or standard care. Patients were followed for 12 months and primary outcomes were reported after 6 months.

**U.S. findings**
As reported by Sciurba et al, 321 patients in the U.S. were randomly assigned on a 2:1 basis to receive Zephyr endobronchial valves (n=220) or standard medical care (n=101). (4, 5) The mean number of valves placed in the endobronchial valve group was 3.8 per patient (range, 1 to 9). The primary effectiveness outcomes were percent change from baseline to 6 months in the FEV1 and distance on the 6-minute walk test. A total of 42 of 220 (19.1%) in the endobronchial valve group and 28 of 101 (27.7%) in the control group had missing data for the primary efficacy outcomes. Of the 70 patients with missing data, 6 had died, 4 were too ill to participate, and 60 dropped out or did not have follow-up within the specified time window. The data analysis was intention-to-treat and missing data were imputed. Primary outcome data at 6 months were as follows:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Endobronchial valve group (n=220)</th>
<th>Control group (n=101)</th>
<th>Between-group difference (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEV1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean absolute percent change</td>
<td>4.3 (1.4 to 7.2)</td>
<td>-2.5 (-5.4 to 0.4)</td>
<td>6.8 (2.1 to 11.5) p=0.005</td>
</tr>
<tr>
<td>from baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Distance on 6-minute walk test</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median change from baseline</td>
<td>9.3 (-0.5 to 19.1)</td>
<td>-10.7 (-29.6 to 8.1)</td>
<td>19.1 (1.3 to 36.8) p=0.02</td>
</tr>
<tr>
<td>(meters)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median absolute percent change</td>
<td>2.5 (-1.1 to 6.1)</td>
<td>-3.2 (-8.9 to 2.4)</td>
<td>5.8 (0.5 to 11.2) p=0.04</td>
</tr>
<tr>
<td>from baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Among the secondary outcomes reported at the 6-month follow-up, quality of life was measured using the St. George’s Respiratory Questionnaire (SGRQ), which ranges from 0 to 100, with a higher score indicating a worse quality of life. At 6 months, the SGRQ score decreased -2.8 points (95% confidence interval [CI], -4.7 to -1.0) in the endobronchial valve group and increased 0.6 points (95% CI, -1.8 to 3.0) in the control group. The between-group difference was -3.4 (95% CI, -6.7 to 0.2), which was statistically significant (p=0.04) but was less than the 4 points generally considered to represent a clinically meaningful difference. (6) According to body plethysmography, the mean change in total lung volume at 6 months was -1.2 (SD=10.6) in the endobronchial valve group and -0.4% (SD=13) in the control group; this difference was not statistically significant, p=0.41. Similarly, changes between groups in residual volume and inspiratory capacity were not statistically significant.

The primary safety variable was a composite measure consisting of 6 major complications (death, empyema, massive hemoptysis, pneumonia distal to valves, pneumothorax or air leak of more than 7 days’ duration or ventilator-dependent respiratory failure for more than 24 hours). The rate by 6 months was 6.1% in the endobronchial group and 1.2% in the control group. The between-group difference was 4.9% (95% CI, 1.0 to 8.8), which was not statistically different (p=0.08) and fell within the prespecified safety criteria. The adverse events to 6 months included 6 deaths (2.8%) in the endobronchial valve group and no deaths in the control group (p=0.19). Between 3 and 12 months, 25 of 214 (11.7%) patients in the endobronchial valve group followed over this time experienced COPD exacerbations; 22 of these events resulted in hospitalization. Over the same time period, 8 of 87 (9.2%) patients in the control group had COPD exacerbations, all of which resulted in hospitalization. The difference in number of exacerbations was not statistically significant. For hemoptysis (other than massive) between 3 and 12 months, there were 13 (6.1%) cases in the endobronchial valve group and none in the control group (p=0.02). Among the 214 patients who received valves and were followed to 12 months, there were 6 cases (2.8%) of valve expectoration, aspiration, or migration and 9 cases (4.2%) of bronchial granulation tissue. Valves were removed in 31 (14%) patients after 1 to 377 days; removal was based on investigators’ discretion; there was no specific protocol.
European findings

Herth et al reported on 171 patients in the European cohort of the VENT; 111 patients were randomized to the endobronchial valve group and 60 patients to the standard care group. (7) During the course of the study, 10 patients died and 4 patients withdrew from the study. The number of patients who were lost to follow-up or missed a visit was 12 at 6 months and 21 at 12 months. A total of 154 of 171 (90%) patients completed the 6-month follow-up and 136 of 171 (80%) completed the 12-month follow-up. Primary outcome data at 6 months in the European cohort were as follows (outcome reporting was slightly different than it was in the U.S. cohort):

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Endobronchial valve group (n=220)</th>
<th>Control group (n=101)</th>
<th>Between-group difference (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1 Mean (SD) absolute percent change from baseline</td>
<td>7 (20)</td>
<td>0.5 (19)</td>
<td>0.067</td>
</tr>
<tr>
<td>Distance on 6-minute walk test</td>
<td>Median (SD) change from baseline (meters)</td>
<td>15 (91)</td>
<td>10 (78)</td>
</tr>
<tr>
<td>Mean (SD) change in cycle ergometry workload change from baseline (watts)</td>
<td>2 (14)</td>
<td>-3 (10)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

SD: standard deviation

At 12 months, mean (SD) change in FEV1 was 6 (26) in the endobronchial valve group and -2 (20) in the control group, p=0.0499. The mean (SD) change in cycle ergometry workload was 1 watt (13) in the endobronchial valve group and -5 watts (12) in the control group, p=0.03. Data on the 6-minute walk test at 12 months were not reported. Twenty percent of randomized patients did not provide data at 12 months.

Findings on the composite safety variable, reported for the U.S. cohort, were not reported for the European cohort. Herth et al reported that serious complications and the rate of COPD exacerbations in the European cohort did not differ significantly between groups, and there were no reported cases of emphysema or massive hemoptysis. Five cases of pneumothorax requiring hospitalization for longer than 7 days were reported in the endobronchial valve group. There were 10 deaths, 6 in the endobronchial valve group and 4 in the control group; none were considered to be related to study procedures. Over the 12-month follow-up period, there were 13 cases of valve expectoration, aspiration or migration; this represented 12% of the 111 patients in the endobronchial valve group. Eight of 13 events occurred in the first 90 days after valve placement.

Six-month outcomes: U.S. and European cohorts

Data from 416 of the 492 (84.6%) patients randomized in both cohorts who received follow-up computed tomography scans at 6 months were reported by Valipour et al in 2013. (8) Of the 416 patients, 284 were in the endobronchial valve group and 132 were in the control group. The authors reported on several outcomes using an intention-to-treat approach; these outcomes were not originally listed as either primary or secondary outcome measures in the Sciurba et al report (4). At 6 months, the mean target lobar volume reduction was significantly higher in patients receiving endobronchial valve therapy than in control patients (-242 mL vs 0.5 mL, p<0.001). Moreover, 42% of patients in the endobronchial valve group and 24.7% of controls had improvement of at least 1 point in the BODE index at 6 months (p<0.001). (The BODE index combines several variables, including the FEV1 and the distance on the 6-minute walk test. A higher score on the BODE index has been found to correlate with an increased risk of death from COPD). Valipour et al did not discuss missing data on the FEV1 or 6-minute walk test measures at 6 months.

Study limitations
A limitation of VENT was lack of blinding, which could have affected performance on the primary efficacy outcomes, eg, it may have affected clinicians’ coaching of patients and/or the degree of effort exerted by patients. In addition, there was a substantial amount of missing data on the 6-month primary efficacy variables in the U.S. cohort, about 28%. Most of the missing data was due to lack of compliance rather than death or illness. Although there was a prespecified plan for handling missing data, with this degree of data missing, findings might not accurately represent outcomes in the population. Moreover, although Herth et al reported that the study had sufficient statistical power, there tended to be wide confidence intervals, indicating an insufficiently large sample size. Also, some between-group differences, though statistically significant, may not be clinically significant, eg, a 7%-8% difference in absolute change from baseline in FEV1. Furthermore, an editorial accompanying publication of the U.S. findings noted that the rate of complications, such as COPD, were higher in the endobronchial valve group, albeit not statistically different. The editorial additionally criticized the study for not standardizing medical treatment for the control group and for possibly providing suboptimal medical therapy for both groups, eg, only 57% of patients received recommended bronchodilators at the beginning of the study, and that the medical therapy was not standardized.

Case series
A 2006 article by Wan and colleagues reported on 98 patients from 9 centers in 7 countries (not including the United States) who received Zephyr endobronchial valves for severe emphysema. Data were obtained from a prospectively-collected multicenter registry. Patients had symptomatic emphysema and shortness of breath on daily activities, despite optimized medical therapy; most were candidates for LVRS at the participating centers. A mean of 4 (SD=1.6) valves were placed per patient (range, 1-8 valves). On average, there was statistically significant improvement in change from baseline to the 90-day follow-up in efficacy variables. For example, the mean absolute change in FEV1 was 0.06 liters (SD=0.21), and the mean absolute change in the 6-minute walk test was 36.9 (SD=90) meters. The p values for change from baseline were 0.007 and less than 0.001, respectively. Among the 98 patients, there were 8 serious complications including 1 death, and 30 patients had other complications including 17 exacerbations of COPD and 5 pneumonias in untreated lobes.

An uncontrolled study published in 2010 by Sterman et al evaluated the IBV Valve for treatment of severe emphysema. Data were collected on 91 patients from 11 sites in the United States. All patients had heterogenous upper-lobe predominant emphysema. The aim of the study was predominantly to study safety of the valve; the primary outcome was the rate of observed migration, erosion, or infection during the first 3 months after placement. Effectiveness and quality of life were secondary outcomes. Patients were followed for up to 12 months.

A total of 609 valves were placed, with a mean of 6.7 valves per patient (range, 3-11). Seven patients withdrew from the study by 6 months; 5 of these withdrawals were due to adverse effects. Regarding the primary safety outcomes, there were no occurrences of valve migration or erosion during the 12-month follow-up. However, there were 2 instances of infection in the first 3 months, 1 episode each of pneumonia and bacterial bronchitis. Eight patients (8.8%) experienced bronchospasm (dyspnea and wheezing) after bronchoscopy; 2 patients had at least one valve removed due to bronchospasm. During the 12-month follow-up, 11 patients (12%) experienced pneumothorax. Three of these had pneumothorax with prolonged air leaks, and a total of 3 patients with pneumothorax died (one each on day 4, day 33 and day 113). There were no statistically significant improvements in the efficacy outcomes. The mean FEV1 was 0.87 liters at baseline (n=91) and 0.83 liters at 3 months (n=79). Among the 76 patients with data on the 6-minute walk test at 3 months, the mean distance walked had increased by 4 feet compared to baseline. However, there was improvement in quality of life, as assessed by the SGRQ. At 3 months, there was a mean decrease of 5.1 points (p=0.01), and 41 of 78 patients with available data (52.6%) were considered responders (a decrease in at least 4 points on the SGRQ).

Section summary: For patients with advanced emphysema, case series and a single unblinded RCT provide insufficient evidence that the technology improves the net health outcome. In the RCT, there was a statistically significant change in FEV1 and in the 6-minute walk distance from baseline to 6
months in the U.S. cohort but not in the European cohort and a statistically significant change in FEV1 at 12 months in the European cohort. Twelve-month data were not reported for the U.S. cohort. Even when statistically significant, the magnitude of the improvements was of uncertain clinical significance. In addition, the numerous adverse events experienced by patients who received endobronchial valves raise concerns about the safety of the treatment.

**Ongoing Clinical Trials**

A search of the Clinicaltrials.gov database on January 10, 2014 identified 3 ongoing RCTs evaluating endobronchial valves. All of the ongoing RCTs are industry-sponsored. They include:

**Evaluation of the IBV® Valve for Emphysema to Improve Lung Function (EMPROVE) (NCT01812447):** This is a multicenter U.S-based RCT comparing endobronchial valves and standard medical management in patients with severe and heterogeneous emphysema with severe dyspnea. The estimated sample size is 270 patients, and the expected date of study completion is September 2015.

**Spiration Valve System for the Treatment of Severe Emphysema (SVS) (NCT01989182):** This multicenter RCT, conducted in China, is comparing endobronchial valves with standard medical management in patients with severe and heterogeneous emphysema with severe dyspnea. The estimated sample size is 100 patients and the expected date of study completion is September 2015.

**Pulmonx Endobronchial Valves Used in Treatment of Emphysema (LIBERATE Study) (NCT01796392):** This is a multicenter U.S-based RCT comparing endobronchial valves and standard medical management in patients with severe and heterogeneous emphysema with severe dyspnea. The estimated sample size is 183 patients and the expected date of study completion is September 2015.

**Clinical Input Received through Physician Specialty Societies and Academic Medical Centers**

In response to requests, input was received through 1 physician specialty society and 3 academic medical centers while this policy was under review for March 2011. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. Those providing input generally agreed that use of endobronchial valves is investigational for the treatment of emphysema. Regarding use of endobronchial valves for treating prolonged air leaks, reviewers acknowledged that only limited case series are available. Of the 4 reviewers, 1 supported the investigational indication, 2 supported the compassionate use of valves for treating prolonged air leaks, and the fourth thought that treatment of prolonged air leaks might be reasonable but had concerns about potential complications.

**Summary**

Endobronchial valves are synthetic devices that are deployed with bronchoscopy into ventilatory airways of the lung for the purpose of controlling airflow. There is insufficient evidence from small uncontrolled studies that endobronchial valves improve health outcomes in patients with persistent air leaks. For patients with advanced emphysema, case series and a single unblinded randomized controlled trial with limitations provide insufficient evidence that the technology improves the net health outcome. Therefore, given the insufficiency of the data, endobronchial valve placement for treatment of prolonged air leaks or emphysema is considered investigational.

**Practice Guidelines, and Position Statements**

In 2011, the British Thoracic Society published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults. (12) The guidelines stated that sufficient evidence has not yet been demonstrated to recommend the routine use of endobronchial valves for treatment of emphysema.
Medicare National Coverage
No national coverage determination.

References

Billing Coding/Physician Documentation Information
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])

Additional Policy Key Words
N/A

Policy Implementation/Update Information
4/1/13 New policy; considered investigational.
4/1/14 No policy statement changes.
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.