**Endobronchial Brachytherapy**

**Policy Statement**

Endobronchial brachytherapy may be considered medically necessary for either of the following clinical situations:

- In patients with primary endobronchial tumors who are not otherwise candidates for surgical resection or external beam radiotherapy due to comorbidities or location of the tumor
- As a palliative therapy for airway obstruction or severe hemoptysis in patients with primary, metastatic, or recurrent endobronchial tumors

Other applications of endobronchial brachytherapy are considered investigational including, but not limited to:

- Its use as a radiation “boost” to curative external beam radiotherapy
- As treatment for asymptomatic recurrences of non-small-cell lung cancer
- In the treatment of hyperplastic granulation tissue

**Policy Guidelines**

Endobronchial brachytherapy is a multistep procedure requiring a series of radiation oncology CPT codes for radiation treatment planning, radiation physics, treatment delivery, and clinical treatment management. CPT codes 77761-77787 describe various types of radiation source application; these codes are used to describe the brachytherapy delivery. In contrast to other types of radiotherapy, endobronchial brachytherapy requires the services of a radiation oncologist, and a pulmonologist or other physician to perform the bronchoscopy and insert the catheter.

There is a CPT code that specifically identifies the catheter placement:

- **31643**: Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application

**Description**

Endobronchial brachytherapy is the delivery of radiotherapy directly to endobronchial lesions, either intraluminally or interstitially, using permanently implanted radioactive seeds or a temporary afterloading implant. The technique permits targeted radiation while minimizing exposure to surrounding radiosensitive structures, such as normal lung, heart, and spinal cord.

**Related Policies**

- N/A

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these
instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

Several bronchoscopes (Food and Drug Administration product code: EOQ) and remote-controlled afterload/radionuclide applicator systems (Food and Drug Administration product code: JAQ) have been cleared for marketing by the Food and Drug Administration through the 510(k) process. Examples of both include the Video Sciences BRS-5000 Video Bronchoscopy with EndoSheath System (Vision-Sciences) and microSelectron (Nucletron), respectively.

**Rationale**

**Background**

**Endobronchial Lesions**

**Brachytherapy**

Endobronchial brachytherapy has been most investigated as a palliative treatment of obstructing primary or metastatic tumors, particularly in non-small-cell lung cancer. Endobronchial brachytherapy has also been used as a tool in curative treatment for some primary bronchial and tracheal tumors. Two to 4 fractions delivered weekly is a typical schedule. The most serious complications described for endobronchial brachytherapy are massive hemoptysis, formation of tracheoesophageal fistulas, bronchospasm, bronchial stenosis, and radiation bronchitis.\(^1\) Median overall survival of these patients is typically less than 9 months.

In the outpatient setting, the patient receives local anesthesia and monitored sedation. A flexible bronchoscope is passed transnasally; a separate port on the bronchoscope allows passage of the afterloading catheter to the target lesion. Once the catheter is placed, the radioisotope can be administered by the high-dose-rate radiotherapy afterloading machine. Patients with potential airway compromise due to bleeding may require treatment with a rigid bronchoscope, which requires general anesthesia and frequently an overnight stay.

**Other Treatments**

Endobronchial brachytherapy represents an approach to the local treatment of endobronchial lesions. Other technologies include electrocoagulation, cryosurgery, laser resection, endosurgery, and endobronchial stent placement. In some instances, the therapies may be used together, such as using laser therapy for initial debulking followed by brachytherapy.

**Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse
events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Endobronchial Brachytherapy as Palliative Treatment**

Many patients with non-small-cell lung cancer (NSCLC) are initially treated with external-beam radiotherapy (EBRT) but ultimately experience local recurrence. Many are not candidates for additional EBRT due to limited tolerance of normal tissue. If symptoms persist after EBRT, endobronchial brachytherapy is well-accepted as short-term palliation for such symptoms as hemoptysis, cough, and dyspnea, and for resolution of obstructive atelectasis or pneumonitis. A 2008 European prospective study reported on 270 patients who had previously received radiotherapy and subsequently were given high-dose-rate (HDR) brachytherapy. Total response rate was 80% for symptoms of dyspnea, cough, hemoptysis, and post-obstructive pneumonia, with a median duration of palliation of 5 months (range, 2-14 months). In a summary of studies of palliative endobronchial brachytherapy between 1985 and 1994, Villanueva et al (1995) reported effective palliation in 60% to 100% of patients.3

A 2008 Cochrane review (updated in 2012) assessing palliative endobronchial brachytherapy for NSCLC analyzed 13 RCTs but did not conduct meta-analyses because of heterogeneity in the doses of radiotherapy delivered, patient characteristics, and outcomes measured.1,4 Reviewers concluded that EBRT alone was more effective for palliation of symptoms than endobronchial brachytherapy alone. Findings did not provide conclusive evidence that endobronchial brachytherapy plus EBRT improved symptom relief, reduced complication rates, or extended survival compared with EBRT alone. In summary, reviewers did not find sufficient evidence to recommend endobronchial brachytherapy as an add-on to first-line EBRT, chemotherapy, or Nd-YAG laser palliative treatment. For patients previously treated with EBRT who remain symptomatic, endobronchial brachytherapy was considered an option.

A 2006 prospective randomized trial from India (N=45) also suggested that endobronchial brachytherapy alone and endobronchial brachytherapy plus EBRT has similar efficacy and safety profiles in the palliative management of NSCLC.5

Ung et al (2006) conducted a systematic review of endobronchial brachytherapy for palliative treatment of NSCLC.6 Based on 29 studies, including 6 randomized trials, reviewers also concluded that EBRT alone was more effective than endobronchial brachytherapy alone for symptom palliation in previously untreated patients. Unlike the Cochrane reviews, however, the Ung review concluded that endobronchial brachytherapy with EBRT seems to provide better symptom relief than EBRT alone, yet the final recommendation was to use endobronchial brachytherapy only for symptomatic recurrent endobronchial obstruction after EBRT.

In 2015, Goldberg et al reported on a prospective, observational cohort study evaluating the quality of life and symptom-related outcomes for 98 patients with locally advanced inoperable lung cancer receiving HDR endobronchial brachytherapy.7 Patients were followed every 3 months for 1 year. Most (78%) were treated for newly diagnosed disease that was inoperable at diagnosis. The overall survival (OS) rate was 13.4% at 12 months. Endobronchial brachytherapy was not associated with OS or quality of life, compared with chemotherapy or EBRT, in multivariable analyses.

Ozkok et al (2008) published a case series from Turkey on the use of HDR endobronchial brachytherapy for palliation of symptoms in 158 patients with 3 lung cancer profiles.8 Group A comprised 43 patients with stage IIIA or IIIB NSCLC who received endobronchial brachytherapy plus EBRT; group B comprised 74 previously untreated patients with incurable, locally advanced lung cancer; and group C comprised 41 patients with symptomatic endobronchial recurrences who had previously received full-dose radiotherapy. Participants in group A were from a previously reported prospective trial (2002); data from these participants were reanalyzed for symptom palliation in the Ozkok report. Not all patients received the intended number of fractions due to patient refusal or deterioration in performance status. A few patients required
more than the prescribed doses due to repetitive obstructive symptoms. Response rates for a
cough, dyspnea, and hemoptysis were measured using the Speiser Symptom Index scoring
system. Response rates in group A were 58% for cough (30% complete response [CR]), 77% for
dyspnea (76% CR), and 100% for hemoptysis (92% CR). Groups B and C had CR rates of 57% and
55% for a cough and 90% and 78% for dyspnea, respectively. Eighteen (11%) patients died of
hemoptysis, with a median time to an event of 7 months. Significant prognostic factors for fatal
hemoptysis were the use of brachytherapy intended as a treatment (as opposed to palliation,
p<0.001), total radiobiologic equivalent dose (p<0.001), and the number of high-dose-rate
endobronchial brachytherapy fractions (p<0.001). The authors concluded that high-dose-rate
endobronchial brachytherapy was effective for palliation of symptoms related to inoperable
lung cancer, either alone or in combination with EBRT. They cautioned that optimal dose,
fractionation, and combination schedule with EBRT were unknown. Further, they stated that any
benefit had to be weighed against potentially serious treatment-related morbidity or mortality.

Although endobronchial brachytherapy is often used to palliate hemoptysis, historically, there
has been concern about an observed association between treatment with endobronchial
brachytherapy and fatal hemoptysis. The largest study retrospectively reviewed 938 patients
treated with external irradiation and/or endobronchial brachytherapy for inoperable NSCLC.10 In
this 1998 study, 101 (10.8%) patients died from massive hemoptysis; 78 (77%) of those who died
had clinical or radiologic evidence of tumor progression while 23 (23%) did not. On multivariate
analysis, intrabronchial tumor extension in the main bronchus, hemoptysis before radiotherapy,
and tumor location in the upper bronchus were independently associated with massive
hemoptysis. A dose-response relation between fraction dose and massive hemoptysis also was
found; in all subgroups, higher incidence of massive hemoptysis was seen after fraction dose of
15 gray (Gy). These data were largely consistent with data from Hennequin et al (1998) who
reported that hemoptysis was most likely due to disease progression, with brachytherapy
facilitating bleeding, rather than directly causing bleeding.11 However, for tumors located in the
upper lobes, brachytherapy may be causal. Tumor location was cited as the most important
factor in predicting pulmonary hemoptysis in a 1992 case series reported by Bedwinek et al, in
which 32% of patients died of massive hemoptysis after brachytherapy.12

Dagnault et al (2010) retrospectively reviewed 81 patients treated with brachytherapy for
symptom palliation due to endobronchial primary lung tumors or metastases.13 Between 2002
and 2007, 81 patients who were not candidates for surgery or EBRT because of poor respiratory
function, medical comorbidities, or previous treatment with thoracic radiation or surgery, were
treated at a single institution. Mean patient age was 66 years (range, 39-87 years). Previous
treatment comprised surgical resection of the primary tumor in 58% of patients, lung
radiotherapy in 44%, and chemotherapy in 41%. After endobronchial brachytherapy, patients
were followed until death or loss to follow-up. Patient characteristics included 59 (73%) with a
lung primary and the remainder with metastatic disease, including primary colorectal cancer
(13%), kidney, gynecologic, or head and neck cancers (4% each), and other cancers (2%).

Presenting symptoms included dyspnea (66%), cough (47%), hemoptysis (28%), and no
symptoms (6%). After brachytherapy, major symptomatic improvement was seen in most
patients: dyspnea improved during or shortly after the end of treatment in 85% of patients;
hemoptysis stopped in all 23 patients; a cough improved in 77% of patients, and 18% remained
stable. At 6-week follow-up, 72% of tumors were evaluable for bronchoscopic response. A visible
bronchoscopic response was evident in 77 patients; for 42 (52%) of 81 patients, the tumor shrank
significantly during treatment. Median survival was 14.7 months; local progression-free survival
(PFS) was 77% at 12 months and 64% at 24 months. For comparison, authors stated that OS for
most patients with inoperable endobronchial tumors or metastasis was less than 6 months. The
incidence of complications was low, and all complications resolved.

Guamaschelli et al (2010) reviewed treatment outcomes of 52 patients with recurrent
endobronchial tumors who underwent palliative high-dose-rate endobronchial brachytherapy
between 1995 and 2005 at a single institution.14 Objective response was assessed by
Endobronchial Brachytherapy

Page 5 of 13

bronchoscopy and chest computed tomography, and subjective clinical response by patient reports. All patients had histologically proven bronchogenic carcinoma, recurrent or persistent symptoms (hemoptysis, cough, dyspnea, or postobstructive pneumonia), previous definitive EBRT, and bronchoscopic evidence of endobronchial obstruction. The mean patient age was 63 years (range, 41-83 years); 37% of patients were women. Tumor histology was non-small-cell in 77% of patients, small cell in 13%, adenoid cystic in 2%, and metastatic in 2%. Patient symptoms before brachytherapy included dyspnea on exertion (79%), cough (89%), hemoptysis (62%), wheezing (52%), dysphagia (8%), chest pain (15%), and shortness of breath (83%). Symptomatic improvement was defined as significant if there was an improvement in 2 or more symptoms and mild if only 1 symptom improved. Forty-eight (92%) patients showed symptomatic improvement.

One patient had worsening hemoptysis, and 2 (4%) of 52 patients did not return for assessment. Median time to symptomatic relapse after the first fraction of brachytherapy was 6 months (range, 1 to >6 months). Complete or partial tumor regression was demonstrated in 44 (85%) patients on repeat bronchoscopy. For the entire cohort, median follow-up was 31 months, and median actual OS from the first brachytherapy session was 7 months (range, 0-55 months). Fifty (96%) patients tolerated treatment without acute, treatment-related complications. Significant treatment-related complications (grade 3 or 4) were reported as possibly occurring in 2 (4%) patients: one developed a pneumothorax 6 weeks after brachytherapy, and another died from hemoptysis 48 hours after treatment (it was unknown whether hemoptysis was due to brachytherapy or to the erosion of tumor into a blood vessel).

A 2013 comparative effectiveness review prepared for the Agency for Healthcare Research and Quality assessed local nonsurgical therapies for symptomatic obstructive NSCLC. 15 For patients with an obstruction due to inoperable NSCLC, 4 RCTs (n=268 patients) examined endobronchial brachytherapy alone or in combination with EBRT or Nd-YAG laser therapy for palliative or curative intent. All RCTs were determined to be of poor quality. Seven single-arm studies (n=740 patients) examined endobronchial brachytherapy alone or in combination with EBRT, stent placement, or chemotherapy plus photodynamic therapy for palliative or curative intent. The evidence was considered “insufficient to permit conclusions on the comparative effectiveness of local nonsurgical therapies for ... inoperable NSCLC patients with endoluminal tumor causing pulmonary symptoms.”

Section Summary: Endobronchial Brachytherapy as Palliative Treatment

Single-arm series and RCTs summarized in systematic reviews comprise the evidence base for endobronchial brachytherapy with palliative intent for NSCLC. Overall, the RCTs were assessed as low-quality, and there is no evidence that endobronchial brachytherapy improved survival. However, the single-arm studies suggested that endobronchial brachytherapy improved symptoms (pulmonary obstruction, hemoptysis), particularly in patients not candidates for EBRT.

Endobronchial Brachytherapy as Primary Treatment

Candidates for primary treatment are principally patients with early-stage endobronchial tumors who are not candidates for surgical resection or EBRT due to comorbidities or tumor location. Most studies have been case series, which reported CR rates of 50% to 80%.16-18

There also have been investigations using brachytherapy to deliver a focused radiation boost to patients undergoing curative EBRT. Because patients usually present with surgically unresectable disease and because NSCLC is unresponsive to chemotherapy, the primary treatment for most patients with NSCLC is typically EBRT.

Aumont-le Guilcher et al (2011) reported on 226 patients with primary NSCLC (endobronchial only) who underwent HDR brachytherapy because of contraindications to surgery and EBRT.19 The patient sample comprised 223 men and 3 women from 9 institutions; mean age was 62 years (range, 40-84 years). Tumor histology was squamous cell carcinoma in 96%, adenocarcinoma in 2%, and other in 2%. Response to HDR brachytherapy at 2 to 3 months was classified as a complete histologic response (disappearance of the lesion by bronchoscopy and negative
biopsy), complete macroscopic response (disappearance of the lesion but no biopsy), partial response (>50% decrease in endobronchial tumor volume), or progression (increase in endobronchial tumor volume or tumor visible on computed tomography scan). At 3 months, complete local response was observed in 213 (94%) patients, and in 137 patients with biopsies, 126 (91%) had a CR. Also, 7 patients had tumor progression, five had a partial response, and one had stable disease. The OS rate was 57% at 2 years and 29% at 5 years. Median survival was 28.6 months. The cancer-specific survival rate was 81% at 2 years and 56% at 5 years. Complications led to treatment interruption in 4.5% of patients. Fatal complications (most commonly fatal hemoptysis) occurred in 6% of patients.

Skowronek et al (2013) reported on a small cohort of 34 patients in Poland who had stage IB, II, or III lung cancer (74% squamous cell carcinoma histology; all distant metastasis-free) who had undergone lobar resection.19 Thirteen (38%) patients developed postoperative recurrence in the bronchial stump, and 21 (72%) patients had histopathologically positive margins after nonradical resection. All patients had dyspnea and cough, and 8 (24%) patients had hemoptysis. Median patient age was 57 years (range, 47-73 years). Median time to recurrence after surgery was 11 months. It was not specified whether patients were candidates for reoperation. Nine patients received HDR endobronchial brachytherapy (total dose, 12 Gy) in combination with EBRT (total dose, 50 Gy), and 25 patients received brachytherapy alone (total dose, 30 Gy). At 1 month, complete local and radiologic response was observed in 25 (74%) patients, with 100% complete remission in the nonradical surgery group. All partial responses occurred in the recurrent tumor group (9 [69%] of 13 patients). Median OS for the entire cohort was 19 months. With a median follow-up of 2 years, the 2-year OS rate was 15% in the group with recurrent tumor and 48% in the nonradical resection group (p=0.05). Adverse events were not reported.

Rochet et al (2013) reported on a cohort of 35 patients in Germany who had stage I, II, or III inoperable NSCLC (31% squamous cell carcinoma histology; all distant metastasis-free) and received primary treatment with HDR endobronchial brachytherapy (median total dose, 15 Gy) in combination with EBRT (median total dose, 50 Gy).20 Mean age was 64 years (range, 45-75 years). With a median follow-up of 26 months, median OS was 39 months. One-, 2-, and 5-year OS rates were 76%, 61%, and 28%, respectively. Median PFS and local PFS were 17 months and 42 months, respectively. In patients without mediastinal node involvement, the 5-year local PFS rate was 56% and 11% with positive mediastinal nodes (p=0.008). Grade 3 adverse events were hemoptysis in 2 patients and necrosis in 1 patient. Fatal hemoptysis in 1 patient resulted from tumor recurrence.

In 2016, Hosni et al reported on a series of 10 patients with endobronchial tumors treated at a single center with endobronchial brachytherapy with curative intent with (n=8) or without (n=2) EBRT.21 Among the 10 patients treated with curative intent; median follow-up was 17 months. For these patients, the 2-year local control rate was 89% (95% confidence interval [CI], 79% to 99%) and the 2-year OS rate was 67% (95% CI, 51% to 83%). Given the high rate of combination therapy, it is difficult to draw conclusions about brachytherapy alone.

**Section Summary: Endobronchial Brachytherapy as Primary Treatment**

For primary treatment (i.e., with intent to improve survival outcomes), the effects of endobronchial brachytherapy on survival outcomes compared with alternative therapies are not well-defined. Additional comparative data are needed.

**Endobronchial Brachytherapy to Treat Hyperplastic Granulation Tissue**

Endobronchial brachytherapy has been investigated to treat hyperplastic granulation tissue causing recurrent airway stenosis after lung transplantation or stent placement. A 2008 case series reported on endobronchial brachytherapy in 8 patients after excision of obstructive granulation tissue; 6 (75%) patients showed a good or excellent subjective early response for the first 6 months.22 A 2006 case series used endobronchial brachytherapy in 5 patients with benign, post-lung transplantation granulation tissue refractory to multiple other bronchoscopic interventions. After a median follow-up of 12 months, 3 (60%) of 5 patients had marked symptom reduction.
improvement. While this case series reported positive outcomes, adequately powered trials are needed to fully evaluate the potential role of endobronchial brachytherapy in the treatment of granulation tissue.

Rahman et al (2010) reported on long-term follow-up for 115 patients who underwent various flexible bronchoscopic therapeutic modalities for the management of benign tracheal stenosis between 2001 and 2009. HDR endobronchial brachytherapy was used in cases of refractory stent-related granulation tissue formation, defined as requiring 3 or more interventions within 6 months due to recurrent granulation tissue formation. All patients presented with signs and symptoms of upper airway obstruction, including shortness of breath, stridor, cough, dyspnea, and wheezing. Stents were placed in 33 patients to restore airway patency, and 28 of them underwent brachytherapy to prevent granulation tissue reformation. All 28 experienced a reduction in therapeutic bronchoscopic procedures after brachytherapy compared with the pretreatment period; no further details about response duration or other outcomes were reported. There were no treatment-related complications. Although this case series reported positive results, small sample size and concerns about outcomes reporting limit conclusions that can be drawn.

Section Summary: Endobronchial Brachytherapy to Treat Hyperplastic Granulation Tissue
The evidence for endobronchial brachytherapy for hyperplastic granulation tissue is limited by sample sizes. The available case series also typically included endobronchial brachytherapy as part of multimodal management, making it difficult to assess the specific contribution of brachytherapy.

Summary of Evidence
For individuals with NSCLC with airway obstruction or severe hemoptysis who receive endobronchial brachytherapy as palliative treatment, the evidence includes single-arm series and RCTs summarized in systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Overall, the RCTs were assessed as low-quality, and provided no evidence that endobronchial brachytherapy improves survival. However, the single-arm studies have suggested that endobronchial brachytherapy improves symptoms (pulmonary obstruction, hemoptysis), particularly in patients who are not candidates for EBRT. If symptoms persist after EBRT, endobronchial brachytherapy is well-accepted as short-term palliation for symptoms such as hemoptysis, cough and dyspnea, and resolution of obstructive atelectasis or pneumonitis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with NSCLC who receive endobronchial brachytherapy as primary treatment, the evidence includes single-arm series. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. For primary treatment (i.e., with intent to improve survival outcomes), the effects of endobronchial brachytherapy on survival outcomes compared with alternative therapies are not well-defined. Additional comparative data are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with endobronchial hyperplastic granulation tissue who receive endobronchial brachytherapy, the evidence includes case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence for endobronchial brachytherapy for hyperplastic granulation tissue is limited. The available case series typically include endobronchial brachytherapy as part of multimodal management, making it difficult to assess the specific contribution of brachytherapy. The evidence is insufficient to determine the effects of the technology on health outcomes.
Practitioner Guidelines and Position Statements

Current National Comprehensive Cancer Network guidelines (v.1.2018) for non-small-cell lung cancer recommend relief of airway obstruction with endobronchial brachytherapy for locoregional recurrence with (1) endobronchial obstruction or (2) severe hemoptysis (category 2A).26

American College of Radiology

The American College of Radiology (ACR) made a number of recommendations in 2013 and 2014 on use of radiotherapy and nonsurgical treatments of lung cancer.

• For nonsurgical treatment of non-small-cell lung cancer in patients with poor performance status or for palliative intent, ACR considered endobronchial brachytherapy “useful for patients with symptomatic endobronchial tumors.”27
• For nonsurgical treatment of non-small-cell lung cancer in patients with good performance status or for definitive intent (no distant metastases), ACR considered endobronchial brachytherapy not appropriate.28 Endobronchial brachytherapy may be appropriate in combination with external-beam radiotherapy (EBRT) for patients who are symptomatic due to endoluminal obstruction (e.g., postobstructive pneumonia).27
• Endobronchial brachytherapy was not included in appropriateness criteria for radiotherapy of small cell lung cancer.29

ACR and American Brachytherapy Society

Practice guidelines published jointly by ACR and the American Brachytherapy Society in 2017 addressed the use of high-dose-rate brachytherapy (≥12 gray per hour) in the treatment of multiple medical conditions, including malignancies in the endobronchial region.30 The guidelines cited studies on the use of high-dose-rate brachytherapy as palliative care and as primary care and noted that brachytherapy might be combined with EBRT.

Both groups also published guidelines in 2017 on the use of low-dose-rate radionuclide brachytherapy, defined as treatment between 4 and 200 centigray per hour.31 The guidelines considered low-dose-rate brachytherapy an appropriate treatment for a number of malignancy types, including those found in the bronchus or trachea. Such treatment may be especially appropriate when used to augment EBRT, or when the target volume may be defined. Both guidelines provided a standard for procedural protocol, as well as a summary of the potential treatment sites of the respective types of brachytherapy.

American College of Chest Physicians

Guidelines on the treatment of a cough as a symptom of lung cancer from the American College of Chest Physicians were updated in 2017.32 The systematic review used to inform the guidelines included a number of low-quality studies and the strength of the recommendations was diminished, accordingly. Acknowledging a lack of studies about the effect of brachytherapy on specific lung cancer symptoms (e.g., cough), the College recommended that endobronchial brachytherapy is used in patients who cannot receive surgery, chemotherapy, or EBRT (grade 2C evidence). Citing the accompanying risk of side effects such as hemoptysis, the College suggested that a pharmacologic therapy trial is considered initially, or, if endobronchial brachytherapy is used, that caregivers administer the lowest dose.

American Brachytherapy Society

In 2016, the Society issued consensus guidelines on thoracic brachytherapy for lung cancer.33 The guidelines included the following recommendations:

• As palliative care for patients with central, obstructive lesions, particularly those who have previously received EBRT.
• Alone or in combination with “endobronchial resection, laser therapy, stenting, and photodynamic therapy.”
• As either “high dose rate or pulsed dose rate with the ability to optimize dose” (low dose rate not recommended).
U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Ultradem Bronchoscopy With Virtual Bronchoscopic Navigation and Endobronchial Ultrasound for the Diagnosis of Peripheral Pulmonary Lesions Without Fluoroscopy: a Randomized Controlled Trial</td>
<td>400</td>
<td>Jun 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT02664259</td>
<td>Phase II Study of Stereotactic Body Radiation Therapy for Un-biopsied Early-Stage Non-Small Cell Lung Cancer</td>
<td>41</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>Unpublished</td>
<td>A Phase III, Multi-centre, Randomized Trial to Evaluate the Symptomatic and Quality of Life Improvements in Lung Cancer Patients Receiving External Beam Radiation Therapy or Without High Dose Rate Intraluminal Brachytherapy</td>
<td>134</td>
<td>Jan 2017 (completed)</td>
</tr>
<tr>
<td>NCT01351116</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: National Clinical Trial

References


### Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Tumor classification
  - Past medical and/or surgical treatment and response
- Operative report(s) or procedure report(s)
- Pathology report(s)
- Radiation treatment plan including: type of brachytherapy, therapy schedule, and number of treatments

### Post Service

- Daily radiation treatment records (if applicable)

### Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>31643</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radionuclide application</td>
</tr>
<tr>
<td></td>
<td>77316</td>
<td>Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)</td>
</tr>
<tr>
<td>Type</td>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>77317</td>
<td>Brachytherapy isodose plan; intermediate (calculation(s) made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)</td>
</tr>
<tr>
<td></td>
<td>77318</td>
<td>Brachytherapy isodose plan; complex (calculation(s) made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)</td>
</tr>
<tr>
<td></td>
<td>77761</td>
<td>Intracavitary radiation source application; simple</td>
</tr>
<tr>
<td></td>
<td>77762</td>
<td>Intracavitary radiation source application; intermediate</td>
</tr>
<tr>
<td></td>
<td>77763</td>
<td>Intracavitary radiation source application; complex</td>
</tr>
<tr>
<td></td>
<td>77770</td>
<td>Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel</td>
</tr>
<tr>
<td></td>
<td>77771</td>
<td>Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels</td>
</tr>
<tr>
<td></td>
<td>77772</td>
<td>Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels</td>
</tr>
<tr>
<td></td>
<td>77790</td>
<td>Supervision, handling, loading of radiation source</td>
</tr>
</tbody>
</table>

**ICD-10 Procedure**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBH001Z</td>
<td>Insertion of Radioactive Element into Tracheobronchial Tree, Open Approach</td>
</tr>
<tr>
<td>OBH031Z</td>
<td>Insertion of Radioactive Element into Tracheobronchial Tree, Percutaneous Approach</td>
</tr>
<tr>
<td>OBH041Z</td>
<td>Insertion of Radioactive Element into Tracheobronchial Tree, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>OBH071Z</td>
<td>Insertion of Radioactive Element into Tracheobronchial Tree, Via Natural or Artificial Opening</td>
</tr>
<tr>
<td>OBH081Z</td>
<td>Insertion of Radioactive Element into Tracheobronchial Tree, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>OBHK01Z</td>
<td>Insertion of Radioactive Element into Right Lung, Open Approach</td>
</tr>
<tr>
<td>OBHK31Z</td>
<td>Insertion of Radioactive Element into Right Lung, Percutaneous Approach</td>
</tr>
<tr>
<td>OBHK41Z</td>
<td>Insertion of Radioactive Element into Right Lung, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>OBHK71Z</td>
<td>Insertion of Radioactive Element into Right Lung, Via Natural or Artificial Opening</td>
</tr>
<tr>
<td>OBHK81Z</td>
<td>Insertion of Radioactive Element into Right Lung, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>OBHL01Z</td>
<td>Insertion of Radioactive Element into Left Lung, Open Approach</td>
</tr>
<tr>
<td>OBHL31Z</td>
<td>Insertion of Radioactive Element into Left Lung, Percutaneous Approach</td>
</tr>
<tr>
<td>OBHL41Z</td>
<td>Insertion of Radioactive Element into Left Lung, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>OBHL71Z</td>
<td>Insertion of Radioactive Element into Left Lung, Via Natural or Artificial Opening</td>
</tr>
<tr>
<td>OBHL81Z</td>
<td>Insertion of Radioactive Element into Left Lung, Via Natural or Artificial Opening Endoscopic</td>
</tr>
</tbody>
</table>

**ICD-10 Diagnosis**

All Diagnoses
Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/30/2015</td>
<td>Policy title change from Brachytherapy for Oncologic Indications</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td></td>
<td>Policy revision with position change</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BCBSA Medical Policy adoption</td>
<td></td>
</tr>
<tr>
<td>02/01/2016</td>
<td>Coding update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>02/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>02/01/2018</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.