8.03.11	Endobronchial Brachytherapy		
Original Policy Date:	June 30, 2015	**Effective Date:**	September 1, 2023
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Policy Statement

I. Endobronchial brachytherapy may be considered **medically necessary** for **either** of the following clinical situations:
   A. In individuals with primary endobronchial tumors who are not otherwise candidates for surgical resection or external-beam radiotherapy due to comorbidities or location of the tumor
   B. As a palliative therapy for airway obstruction or severe hemoptysis in individuals with primary, metastatic, or recurrent endobronchial tumors

II. Other applications of endobronchial brachytherapy are considered **investigational** including, but not limited to:
   A. Its use as a radiation "boost" to curative external-beam radiotherapy
   B. As a treatment for asymptomatic recurrences of non-small-cell lung cancer
   C. In the treatment of hyperplastic granulation tissue

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

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. Unlike 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.

Remote afterloading brachytherapy systems automatically administer a radioisotope directly to cancerous tissue, thereby minimizing the radiation dose to surrounding tissue and eliminating the radiation exposure to hospital staff. The amount of the radiation dose varies with the brachytherapy method chosen for treatment delivery: low-dose-rate (LDR) brachytherapy uses an implanted source that delivers a dose of 40 to 60 centigrays (cGy) per hour over several days; high-dose-rate (HDR) brachytherapy uses a traveling (stepping) source that delivers a dose greater than 100 cGy per minute for 5 to 30 minutes; pulsed-dose-rate (PDR) brachytherapy uses a cable-driven source delivering a dose of up to about 300 cGy per hour for 10 to 30 minutes, repeated over several days.

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

The following codes may be used for this application:

- **77261**: Therapeutic radiology treatment planning; simple
- **77262**: Therapeutic radiology treatment planning; intermediate
- **77263**: Therapeutic radiology treatment planning; complex
- **31643**: Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
- **77295**: 3-dimensional radiotherapy plan, including dose-volume histograms

- **77316**: Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)
- **77317**: Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
- **77318**: Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
- **77370**: Special medical radiation physics consultation
- **77470**: Special treatment procedure (e.g., total body irradiation, hemibody radiation, per oral or endocavitary irradiation)
- **77790**: Supervision, handling, loading of radiation source
- **77761**: Intracavitary radiation source application; simple
- **77762**: Intracavitary radiation source application; intermediate
- **77763**: Intracavitary radiation source application; complex
- **77778**: Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
- **77770**: Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
- **77771**: Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
- **77772**: Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels
- **77014**: Computed tomography guidance for placement of radiation therapy fields
- **77417**: Therapeutic radiology port image(s)
- **77387**: Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
- **G6001**: Ultrasonic guidance for placement of radiation therapy fields
- **G6002**: Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy
- **G6017**: Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

Allowable Codes and Frequencies for Brachytherapy

Description	Code	Maximum per course of treatment	Notes
Clinical Treatment Planning	77261, 77262 or 77263	1	When used as standalone or with external beam, only one plan is allowed.
Simulation	77280, 77285, 77290	5	May not be billed with 77301
Verification Simulation	77280	5	May not be billed with 77301
Respiratory Motion Management	77293	0	Not needed for brachytherapy alone
3D CRT Plan	77295	1 per insertion, max 5	May not be billed with 77301 or with 77316/77317/77318
Brachytherapy Isodose Plan	77316, 77317 or 77318	1 per insertion, max 5	cannot be billed along with 77295
Special Radiation Physics Consult	77370	0	May allow x 1; documentation of medical necessity required
Special MD Consultation (Special Tx Procedure)	77470	1	May allow x 1; documentation of medical necessity required for more than 1 unit
Supervision, Handling, Loading of Radiation Source	77790	1	May not be billed with 77761, 77762, 77763, 77770, 77771, 77772 or 77778

Description	Code	Maximum per course of treatment	Notes
Application of Radiation Sources: LDR Brachytherapy	77761, 77762, 77763, 77778	1	May not be billed with 77770, 77771, 77772
Application of Radiation Sources: HDR Brachytherapy	77770, 77771, 77772	4	Only one delivery code allowed per day per course of therapy. May not be billed with 77761, 77762, 77763, 77778, 77790.
High Dose Rate Electronic Brachytherapy, per fraction	0394T-0395T	0	Investigational for the treatment of skin lesions.
Placement of Radiotherapy Afterloading Catheters	19296, 19297, 19298	1	

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

- Radiation Oncology

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 (U.S. Food and Drug Administration product code: EOQ) and remote-controlled afterload/radionuclide applicator systems (U.S. Food and Drug Administration product code: JAQ) have been cleared for marketing by the U.S. 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 primarily investigated as a palliative treatment of obstructing primary or metastatic tumors, particularly in non-small cell lung cancer.[1,2,] Endobronchial brachytherapy has also been used as a tool in the curative treatment for some primary bronchial and tracheal tumors. Two to 4 fractions delivered weekly is a typical schedule. Median overall survival of patients with obstructing endobronchial tumors 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 is an approach to the local treatment of endobronchial lesions. Other technologies include electrocoagulation, cryosurgery, laser resection, endosurgery, and endo-bronchial stent placement. In some instances, the therapies may be used together, such as 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 the 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 a 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 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Endobronchial Brachytherapy as Palliative Treatment

Clinical Context and Therapy Purpose

The purpose of endobronchial brachytherapy for palliation of individuals who have obstructive lesions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with non-small cell lung cancer (NSCLC) with airway obstruction or severe hemoptysis.

Many patients with 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.

Interventions

The therapy being considered is endobronchial brachytherapy as palliative treatment.

Comparators

The following practices and treatments are currently being used for the palliative treatment of NSCLC with airway obstruction or severe hemoptysis: EBRT, laser resection, surgical resection, and palliative care.

Outcomes

The general outcomes of interest are overall survival (OS), symptoms, morbid events, and treatment-related morbidity. Specific benefits include palliation of obstructive symptoms, avoidance of blood loss due to hemoptysis, and avoidance of adverse events associated with more invasive therapies. Specific harms may occur early due to immediate procedure-related complications. Late-occurring and the most serious complications described for endobronchial brachytherapy are massive hemoptyses, the formation of tracheoesophageal fistulas, bronchospasm, bronchial stenosis, radiation bronchitis, and palliative care.[3,]The duration of follow-up for advanced malignant lesions treated with endobronchial brachytherapy is weeks to months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

A comparative effectiveness review by Ratko et al (2013), prepared for the Agency for Healthcare Research and Quality, assessed local nonsurgical therapies for symptomatic obstructive NSCLC.[4,] For patients with an obstruction due to inoperable NSCLC, 4 RCTs (N=268 patients) examined endobronchial brachytherapy alone or in combination with EBRT or neodymium-doped yttrium aluminum garnet (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."

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.[3,5,] 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. Additionally, 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.

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 et al (2006) review concluded that endobronchial brachytherapy plus 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.

Randomized Controlled Trials

Mallick et al (2006), in a prospective randomized trial from India (N=45), suggested that endobronchial brachytherapy alone and endobronchial brachytherapy plus EBRT have similar efficacy and safety profiles in the palliative management of NSCLC.[7,]A multicenter randomized controlled trial of EBRT with or without endobronchial brachytherapy in patients with advanced NSCLC with endobronchial disease did not indicate a difference between groups in 6-week improvement in overall lung cancer symptoms; however, the study did not achieve its sample size requirement (N=134 patients out of 250-patient planned sample size) due to slow accrual.[8,] Patient-reported hemoptysis scores were significantly improved in the combination arm (p=.03).

Prospective Nonrandomized Studies

Goldberg et al (2015) 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 high-dose rate (HDR) endobronchial brachytherapy.[9,] Patients were followed every 3 months for 1 year. Most (78%) were treated for a newly diagnosed disease that was inoperable at diagnosis. The OS rate was 13.4% at 12 months. Endobronchial brachytherapy was not associated with longer OS or improved 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 brachy-therapy for palliation of symptoms in 158 patients with 3 lung cancer profiles.[10,] 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 by Gejerman et al (2002)[11,]; data from these participants were reanalyzed for symptom palliation in the Ozkok et al (2008) 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 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 cough and 90% and 78% for dyspnea, respectively. Eighteen (11%) patients died of hemoptysis, with a median time to event of 7 months. Significant prognostic factors for fatal hemoptysis were the use of brachytherapy intended as a treatment (as opposed to palliation, p<.001), total radiobiologic equivalent dose (p<.001), and the number of HDR endobronchial brachytherapy fractions (p<.001). The authors concluded that HDR 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.

Retrospective Nonrandomized Studies

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.[12,] In this study, Langendijk et al (1998) reported that 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, a 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.[13,] 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 case series reported by Bedwinek et al (1992), in which 32% of patients died of massive hemoptysis after brachytherapy.[14,]

Dagnault et al (2010) retrospectively reviewed 81 patients treated with brachytherapy for symptom palliation due to endobronchial primary lung tumors or metastases.[15,] 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 to 87 years). Previous treatment included 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 cancer 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; 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, the authors stated that OS estimates for most patients with inoperable endobronchial tumors or metastases were less than 6 months. The incidence of complications was low, and all complications resolved.

Guarnaschelli et al (2010) reviewed treatment outcomes of 52 patients with recurrent endobronchial tumors who underwent palliative HDR endobronchial brachytherapy between 1995 and 2005 at a single institution.[16,] Objective response was assessed by bronchoscopy and chest computed tomography, and subjective clinical response by patient reports. All patients had histologically confirmed bronchogenic carcinoma, recurrent or persistent symptoms (hemoptysis, cough, dyspnea, or postobstructive pneumonia), previous definitive EBRT, and bronchoscopic evidence of endo-

bronchial obstruction. The mean patient age was 63 years (range, 41 to 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 symptom reductions. One patient had worsening hemoptysis, and 2 (4%) of 52 patients did not return for assessment. Median time to symptom relapse after the first fraction of brachytherapy was 6 months (range, 1 to >6 months). Complete or partial tumor regression was confirmed in 44 (85%) patients on repeat bronchoscopy. For the entire cohort, the median follow-up was 31 months, and median actutimes OS from the first brachytherapy session was 7 months (range, 0 to 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: 1 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).

Soror et al (2021) conducted a single-center retrospective review of palliative HDR endobronchial brachytherapy in 347 patients with lung cancer.[17,] Prominent symptoms at the time of brachytherapy included dyspnea (56.2%), hemoptysis (21.9%), and cough (4.6%). Most patients (78.9%) had been diagnosed within the prior 18 months, and the median study follow-up was 13.4 months. Complete symptom relief or major improvement in symptoms was reported in 28% and 59.7% of patients, respectively. Complete or major symptom improvement was common in patients with hemoptysis (90.7%) or airway obstruction (90.9%). The OS rate was 55.2% at 1 year, 18.3% at 2 years, and 3.5% at 5 years.

Section Summary: Endobronchial Brachytherapy as Palliative Treatment

Single-arm series and RCTs summarized in systematic reviews comprise the evidence base for use of 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 reduced symptoms (pulmonary obstruction, hemoptysis), particularly in patients not candidates for EBRT.

Endobronchial Brachytherapy as Primary Treatment

Clinical Context and Therapy Purpose

The purpose of endobronchial brachytherapy as primary treatment for individuals who have NSCLC is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with NSCLC and early-stage endobronchial tumors who are not candidates for surgical resection or EBRT due to comorbidities or tumor location.

Interventions

The therapy being considered is endobronchial brachytherapy as primary treatment.

There also have been investigations using brachytherapy to deliver a focused radiation boost to patients undergoing curative EBRT.

Comparators

The following practices and treatments are currently being used to treat NSCLC: EBRT and surgical resection.

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.

Outcomes

The general outcomes of interest are OS, symptoms, morbid events, and treatment-related morbidity. Specific benefits include avoidance of blood loss due to hemoptysis and avoidance of adverse events associated with more invasive therapies. Specific harms may occur early due to immediate procedure-related complications. Late-occurring and the most serious complications described for endobronchial brachytherapy are massive hemoptyses, the formation of trachea-esophageal fistulas, bronchospasm, bronchial stenosis, radiation bronchitis, and palliative care.[3,]The duration of follow-up for early-stage lesions treated with endobronchial brachytherapy is 1 to 5 years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Most studies have been case series, which have reported CR rates of 50% to 80%.[18,19,20,]

Nonrandomized studies

A phase 2 clinical trial conducted at a single center in China enrolled patients with inoperable or unresectable stage III NSCLC to receive HDR endobronchial brachytherapy in combination with intensity-modulated radiation therapy to involved regional lymph nodes, with or without concurrent or sequential chemotherapy.[21,] The primary endpoint was 5-year OS. Among 83 patients enrolled, 5 did not undergo treatment due to revised staging or unspecified economic reasons and 3 were lost to follow-up. Among 75 patients included in the final analysis, median age was 64 years; most patients were male (74.7%), had an Eastern Cooperative Oncology Group performance status of 1 (62.7%), and underwent concurrent or sequential chemotherapy (96%). With median follow-up of 53.7 months, 5-year OS was 44.5% (95% confidence interval [CI], 33.8% to 58.6%) and median OS was 38.0 months (95% CI, 26.1 to 49.8). No major procedure-related complications were reported; minor complications included asymptomatic pneumothorax (16%), bleeding without hemoptysis or hemothorax (20%), and pain (9.3%).

Case Series

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.[22,] The patient sample comprised 223 men and 3 women from 9 institutions; the mean age was 62 years (range, 40 to 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 endo-bronchial 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, 5 had a partial response, and 1 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) and had undergone lobar resection.[23,] 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 to 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% CR 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=.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).[24,] Mean age was 64 years (range, 45 to 75 years). With a median follow-up of 26 months, the 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=.008). Grade 3 adverse events were hemoptysis in 2 patients and necrosis in 1 patient. Fatal hemoptysis in 1 patient resulted from tumor recurrence.

Hosni et al (2016) 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.[25,] Among the 10 patients treated with curative intent, the median follow-up was 17 months. For these patients, the 2-year local control rate was 89% (95% 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.

Ji et al (2021) reported retrospective outcomes of 99 patients with unresectable early-stage NSCLC who received low dose ablative brachytherapy with radioactive seed implantation.[26,] The median follow-up was 46.3 months. At 1, 3, and 5 years, OS was 96.7%, 70.1%, and 54.4%, respectively and local control rates were 89.1%, 77.5%, and 75.7%, respectively.

Yoon et al (2021) reported on a series of 25 patients with centrally located lung tumors with HDR ablative brachytherapy.[27,] After a median follow-up of 19 months, 2-year local tumor control was 96.2%, PFS was 29.7%, and OS was 65.5%. Adverse effects included 1 minor pulmonary hemorrhage, 4 major pneumothorax, and 13 minor pneumothorax.

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. A non-randomized prospective study suggested clinical benefit in patients with inoperable or unresectable stage III NSCLC undergoing endobronchial brachytherapy with concomitant radiation to involved lymph nodes and chemotherapy. Additional comparative data are needed.

Endobronchial Brachytherapy to Treat Hyperplastic Granulation Tissue

Clinical Context and Therapy Purpose

The purpose of endobronchial brachytherapy in individuals who have endobronchial hyperplastic granulation tissue is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with endobronchial hyperplastic granulation tissue causing recurrent airway stenosis after lung transplantation or stent placement.

Interventions

The therapy being considered is endobronchial brachytherapy.

Comparators

The following practices and treatments are currently being used to treat endobronchial hyperplastic granulation tissue: surgical resection and other endobronchial therapies.

Outcomes

The general outcomes of interest are symptoms, morbid events (e.g., recurrence of central airway obstructions), and treatment-related morbidity. Specific benefits include avoidance of blood loss due to hemoptysis and avoidance of adverse events associated with more invasive therapies. Specific harms may occur early due to immediate procedure-related complications. The duration of follow-up for hyperplastic granulation tissue treated with endobronchial brachytherapy is weeks to months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic reviews

Razmjoo et al (2023) performed a systematic review of 9 case reports and series (N=69) published through October 2022 describing outcomes of endobronchial brachytherapy in patients with recurrent, nonmalignant granulation tissue-induced tracheal stenosis.[28,] Most cases were related to lung transplantation (n=31) or intubation (n=29); median follow-up ranged from 4 to 45 months, and reported success rates (defined as patent airway at most recent follow-up or decreased endo-bronchial interventions following brachytherapy) ranged from 12.5% to 100%.

Case Series

Tendulker et al (2008) reported on a case series assessing 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.[29,] In another case series, Madu et al (2006) used endobronchial brachytherapy to treat 5 patients with benign, post-lung transplantation granulation tissue refractory to multiple other bronchoscopic interventions.[30,] After a median follow-up of 12 months, 3 (60%) of 5 patients had marked symptom improvement.

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.[31] High-dose rate endobronchial brachytherapy was used in cases defined as requiring 3 or more interventions within 6 months due to refractory stent-related 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. Small sample size and concerns about outcomes reporting limit conclusions that can be drawn from this series.

Section Summary: Endobronchial Brachytherapy to Treat Hyperplastic Granulation Tissue

The evidence for endobronchial brachytherapy for hyperplastic granulation tissue consists of case series and a systematic review of case series, and is limited by sample sizes. The systematic review did not include pooled analysis and variable success rates, with differing definitions, were reported. The available case series also typically included endobronchial brachytherapy as part of multimodal management, making it difficult to assess the specific contribution of brachytherapy.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Brachytherapy Society

In 2016, the American Brachytherapy Society issued consensus guidelines on thoracic brachytherapy for lung cancer.[32] The guidelines included the following recommendations:

- As palliative care for patients with central, obstructive lesions, particularly those who have previously received external-beam radiotherapy (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).

American College of Chest Physicians

In 2017, guidelines on the treatment of a cough as a symptom of lung cancer from the American College of Chest Physicians were updated.[33] The systematic review used to inform the guidelines included a number of low-quality studies and the strength of the recommendations were 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 be 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 be considered initially, or, if endobronchial brachytherapy is used, that caregivers administer the lowest dose.

American College of Radiology & American Brachytherapy Society

In 2017, the practice guidelines published jointly by American College of Radiology and the American Brachytherapy Society 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.[34,] 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.

In 2017, both groups also published guidelines on the use of low-dose-rate radionuclide brachytherapy, defined as a treatment between 4 and 200 centigray per hour.[35,] 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 sets of joint guidelines provided a standard for procedural protocol, as well as a summary of the potential treatment sites of the respective types of brachytherapy.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network Guidelines (v. 3.2023) for non-small cell lung cancer include EBRT and brachytherapy as treatment options for severe hemoptysis or endobronchial obstruction in locoregional recurrent disease or symptomatic local disease (category 2A).[36,]

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03290534[a]	Feasibility Study to Treat Lung Cancer With the Permanently Implantable LDR CivaSheet®	40	Dec 2023

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

Please provide the following documentation:

- (click here >>>) Radiation Oncology – Prior Authorization fax form
- (click here >>>) Radiation Oncology – Post Service fax form

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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements

are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
	55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
	76873	Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)
	77014	Computed tomography guidance for placement of radiation therapy fields
	77261	Therapeutic radiology treatment planning; simple
	77262	Therapeutic radiology treatment planning; intermediate
	77263	Therapeutic radiology treatment planning; complex
	77280	Therapeutic radiology simulation-aided field setting; simple
	77285	Therapeutic radiology simulation-aided field setting; intermediate
	77290	Therapeutic radiology simulation-aided field setting; complex
	77295	3-dimensional radiotherapy plan, including dose-volume histograms
	77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)
	77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
	77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
	77370	Special medical radiation physics consultation
	77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
	77417	Therapeutic radiology port image(s)
	77470	Special treatment procedure (e.g., total body irradiation, hemibody radiation, per oral or endocavitary irradiation)
	77761	Intracavitary radiation source application; simple
	77762	Intracavitary radiation source application; intermediate
	77763	Intracavitary radiation source application; complex
	77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
	77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
	77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels
	77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
	77790	Supervision, handling, loading of radiation source
	77799	Unlisted procedure, clinical brachytherapy

Type	Code	Description
HCPCS	G6001	Ultrasonic guidance for placement of radiation therapy fields
	G6002	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy
	G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

Policy History

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

Effective Date	Action
06/30/2015	Policy title change from Brachytherapy for Oncologic Indications Policy revision with position change BCBSA Medical Policy adoption
02/01/2016	Coding update
02/01/2017	Policy revision without position change
02/01/2018	Policy revision without position change
09/01/2018	Policy revision without position change
09/01/2019	Policy revision without position change
10/01/2020	Annual review. No change to policy statement. Literature review updated. Coding update.
11/20/2020	No change to policy statement. Policy guidelines updated. Coding update.
08/01/2021	Annual review. Policy statement and guidelines updated.
12/01/2021	Administrative update. No change to policy statement. Policy guidelines and literature updated.
08/01/2022	Annual review. No change to policy statement.
09/01/2022	Administrative update. Policy statement and literature updated.
09/01/2023	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

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 and Feedback (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 at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Endobronchial Brachytherapy 8.03.11 **Policy Statement:** I. Endobronchial brachytherapy may be considered **medically necessary** for **either** of the following clinical situations: A. In individuals with primary endobronchial tumors who are not otherwise candidates for surgical resection or external-beam radiotherapy due to comorbidities or location of the tumor B. As a palliative therapy for airway obstruction or severe hemoptysis in individuals with primary, metastatic, or recurrent endobronchial tumors II. Other applications of endobronchial brachytherapy are considered **investigational** including, but not limited to: A. Its use as a radiation "boost" to curative external-beam radiotherapy B. As a treatment for asymptomatic recurrences of non-small-cell lung cancer C. In the treatment of hyperplastic granulation tissue	**Endobronchial Brachytherapy 8.03.11** **Policy Statement:** I. Endobronchial brachytherapy may be considered **medically necessary** for **either** of the following clinical situations: A. In individuals with primary endobronchial tumors who are not otherwise candidates for surgical resection or external-beam radiotherapy due to comorbidities or location of the tumor B. As a palliative therapy for airway obstruction or severe hemoptysis in individuals with primary, metastatic, or recurrent endobronchial tumors II. Other applications of endobronchial brachytherapy are considered **investigational** including, but not limited to: A. Its use as a radiation "boost" to curative external-beam radiotherapy B. As a treatment for asymptomatic recurrences of non-small-cell lung cancer C. In the treatment of hyperplastic granulation tissue