6.01.58	Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer		
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Policy Statement

I. Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) may be considered **medically necessary** for the evaluation of peripheral pulmonary lesions in individuals with suspected lung cancer when **all** of the following criteria are met:
   A. Tissue biopsy of the peripheral pulmonary lesion is required for diagnosis (see Policy Guidelines section);
   B. The peripheral pulmonary lesion is not accessible using standard bronchoscopic techniques.

II. EBUS-TBNA is considered **medically necessary** for mediastinal staging in individuals with diagnosed lung cancer when **all** of the following criteria are met:
   A. The individual is suitable and willing to undergo specific treatment for lung cancer, with either curative or palliative intent (see Policy Guidelines section);
   B. Tissue biopsy of abnormal mediastinal lymph nodes seen on imaging is required for staging and specific treatment planning (see Policy Guidelines section);
   C. Abnormal lymph nodes seen on imaging are accessible by EBUS-TBNA.

III. Endobronchial ultrasound is considered **investigational** for diagnosis and staging of lung cancer when the above criteria are not met.

IV. Endobronchial ultrasound is considered **investigational** for **all** other indications.

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

Policy Guidelines

Diagnosis and Staging Guidelines

The American College of Chest Physicians published comprehensive, evidence-based clinical practice guidelines on the diagnosis and management of lung cancer in 2013 (Rivera et al, 2013). Key elements of those guidelines relevant to this policy are outlined next.

The general approach to patients who are suspected of having lung cancer begins with a comprehensive history and physical examination. Imaging studies will include a computed tomography (CT) scan of the chest and a whole body positron emission tomography (PET) or PET-CT study to seek extrathoracic lesions. A patient's suitability and desire for curative treatment of a proven lung cancer are among the chief considerations in choosing among subsequent management options. These factors, in turn, will guide the approach to establishing a diagnosis and staging the disease, as follows:

1. Some individuals may prefer no treatment, particularly those with life-limiting comorbid conditions. In such individuals, neither surgical biopsy nor staging is justified. Aggressive surveillance using serial CT may be used to monitor symptoms for palliation.
2. Two categories of patients, who could potentially benefit from curative surgical resection based on the presence of a solitary, locally confined pulmonary lesion and documented absence of extrathoracic metastatic disease, will not proceed to surgery for completely different reasons.
   a. One group would be considered ineligible for surgery due to sufficiently impaired cardiopulmonary function or other comorbidity that precludes general anesthesia.

b. A second group of individuals would otherwise be eligible for curative surgery but for personal reasons refuse surgical resection.

For either category of patients listed above, surgical diagnostic and staging procedures are contraindicated. Their options include functional imaging (PET, PET-CT, magnetic resonance imaging), CT scan surveillance, and needle-based nonsurgical biopsy, including guided bronchoscopic procedures such as endobronchial ultrasound (EBUS).

3. Patients who are candidates for curative surgical resection by virtue of documented (PET, PET-CT) absence of distant metastatic lesions, locally confined single tumors, and otherwise sound physical condition are eligible for any type of diagnostic and staging procedure.
4. In patients suspected of having lung cancer based on radiographic imaging (CT), functional imaging (PET, PET-CT), and clinical findings (signs and symptoms of lung cancer), a presumptive diagnosis must be confirmed, preferably by the least invasive method, as dictated by the patient's presentation and desire for definitive treatment.
5. For patients with extensive mediastinal infiltration of tumor and no distant metastases, it is suggested that radiographic (CT) assessment of the mediastinal stage is usually sufficient without invasive confirmation.
6. In patients with discrete mediastinal lymph node enlargement (and no distant metastases) with or without PET uptake in mediastinal nodes, invasive staging of the mediastinum is recommended over staging by imaging alone.

Coding

There is CPT coding specifically for endobronchial ultrasound:

- **31652**: Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures
- **31653**: Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures

There is also an add-on code for EBUS of peripheral lesions:

- **31654**: Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to code for primary procedure[s])

Description

Endobronchial ultrasound (EBUS) is an imaging technique for adjunctive use with standard flexible bronchoscopy. It provides an ultrasound-generated image of the lungs beyond the airway walls, extending to peribronchial structures and distal peripheral lung lesions. The purpose of EBUS is to facilitate navigation to distal regions of the lungs and biopsy of peripheral pulmonary nodules; especially suspected cancerous lesions. Another intended use of EBUS is to localize and facilitate biopsy of the mediastinal lymph nodes as part of staging for non-small-cell lung cancer. Both techniques primarily use transbronchial needle aspiration (TBNA) of lesions to obtain tissue samples.

Related Policies

- Electromagnetic Navigation Bronchoscopy

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

A number of instruments are commercially available to perform EBUS-TBNA for diagnosis and staging of lung cancer. All have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process and are shown in Table 1.

Table 1. FDA-Cleared Instruments Used to Perform EBUS-TBNA

Device Name	Manufacture	Date Cleared	510(k)	Indications
EVIS EXERA Bronchofibervideoscope, Olympus BF type UC160F-OL8 bronchoscope and its diagnostic ultrasound transducer	Olympus Medical Systems	Aug 2004	K042140	To provide real-time endoscopic US imaging and US-guided FNA, including the upper airways and tracheobronchial tree
EU-M60 EUS EXERA Endoscopic Ultrasound Center	Olympus Medical Systems	Dec 2004	K04327	To acquire and to display high-resolution and high-penetration, real-time endoscopic US B-mode 2D and 3D images, including the upper airways and tracheobronchial tree
XBF-UC180F-DT8 Ultrasonic Bronchofibervideoscope and the ALOKA SSD-Alpha 5/10 Ultrasound System	Olympus Medical Systems	Jul 2007	K070983	To provide real-time endoscopic US imaging and US-guided FNA including the upper airways and tracheobronchial tree
SonoTip® II EBUS-TBNA Needle System	Medi-Globe	May 2009	K091257	For US-guided FNA of submucosal and extraluminal lesions of the tracheobronchial tree
EchoTip® Ultra High Definition Endobronchial Ultrasound Needle	Cook Medical	Jan 2010	K093195	For use in conjunction with an EBUS endoscope to gain access to and sample submucosal and extramural lesions within or adjacent to the tracheobronchial tree through the accessory channel of an EBUS for FNA
PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus endoscopic ultrasound	PENTAX Medical	Apr 2014	K131946	To provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the pulmonary tract including but not restricted to the nasal passages, pharynx, larynx, trachea, bronchial tree (including access beyond the stem), and underlying areas

Device Name	Manufacture	Date Cleared	510(k)	Indications
SonoTip® Pro and Pro Flex EBUS-TBNA Needle System	Medi-Globe	May 2014	K133763	Intended for US-guided FNA of submucosal and extraluminal lesions of the tracheobronchial tree and gastrointestinal tract (e.g., lymph nodes, abnormal tissue in the mediastinum)
Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle	Boston Scientific	Nov 2015	K151315	For use with EBUS endoscopes for US-guided FNA of the submucosal and extramural lesions of the tracheobronchial tree

EBUS: endobronchial ultrasound; EUS: endoscopic ultrasound; FDA: Food and Drug Administration; FNA: fine-needle aspiration; TBNA: transbronchial needle aspiration; US: ultrasound.

Rationale

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

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.

Diagnosis of Lung Cancer

Clinical Context and Test Purpose

The purpose of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in individuals who have pulmonary lesions and suspected lung cancer is to isolate and biopsy the lesions in order to diagnose and stage detected cancers.

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

Populations

The relevant population of interest is individuals with peripheral pulmonary lesions (PPLs) and suspected lung cancer.

Interventions

The intervention of interest is EBUS-TBNA for diagnosis.

Comparators
Because EBUS is intended as an adjunct to standard bronchoscopic techniques, the primary comparator is flexible bronchoscopy with TBNA. Other methods for determining whether PPLs are cancerous include: transthoracic (percutaneous) needle aspiration using computed tomography (CT) guidance for lesions outside the reach of traditional bronchoscopy, mediastinoscopy, or surgical lung biopsy.

Outcomes
Outcomes of interest for diagnostic accuracy include test accuracy, test validity (e.g., sensitivity, specificity) and morbid events from testing (e.g., pneumothorax and chest tube insertion rates). The primary outcomes of interest for clinical utility are overall survival and disease-specific survival's. An EBUS-TBNA would be performed after PPLs were identified or when a prior less invasive test was inconclusive.

Study Selection Criteria
For the evaluation of clinical validity of EBUS-TBNA for the diagnosis of cancer, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews
A substantial body of literature exists on the use of radial probe EBUS to diagnose lung cancer in individuals with solitary pulmonary nodules or lesions. Several systematic reviews of the literature have been published. Appendix Table 1 provides a crosswalk of studies included in select reviews. Han et al (2018) published a systematic review and meta-analysis comparing radial EBUS and CT-guided transthoracic needle biopsy for the diagnosis of pulmonary lesions 3 cm or smaller.[8,] Twenty-four studies were identified, 9 for EBUS (813 procedures) and 15 for CT (3463 procedures). The pooled diagnostic yield was 75% for EBUS and 93% for CT. For pulmonary lesions 2 cm or smaller, the pooled diagnostic yield was 66% and 92% for EBUS and CT, respectively. Complications were less common for EBUS than for CT; only 10 cases of pneumothorax were reported for EBUS while 660 were reported for CT. The review was limited by the following: (1) all EBUS studies were conducted in the same country, (2) study quality was not uniform, (3) different imaging tools were used in the CT group, and (4) possible study selection bias.

Ali et al (2017) published a systematic review and meta-analysis of studies on the accuracy of radial probe EBUS for diagnosing PPLs.[9,] Fifty-seven studies reporting on 7872 lesions met the eligibility criteria. The pooled data on diagnostic yield, using 54 studies, was 70.6%. In a subgroup analysis of 25 prospective studies (n=2920 lesions), the pooled diagnostic yield was 72.3% (95% confidence interval [CI], 67.5% to 76.8%). In the 28 studies that reported diagnostic yield separately by lesion size, pooled diagnostic yield was 60.5% for lesions 2 cm or smaller and 75% (95% CI, 72.1% to 79.2%) for lesions greater than 2 cm. The overall complication rate was 2.8%. There was a total of 160 reported complications, 82 pneumothoraxes, 61 bleeds, and 17 cases of pneumonia.

The performance of radial probe EBUS in the Ali et al (2017) meta-analysis appears to be at least as high as flexible bronchoscopy for peripheral nodules as reported in an earlier meta-analysis by the American College of Chest Physicians (ACCP; diagnostic sensitivity, 33% for lesions less than 2 cm, 62% for lesions greater than 2 cm, 57% for all peripheral lesions), which is discussed below.[1,]

A systematic review and meta-analysis by Ye et al (2017) focused on fluoroscopy guidance.[10] Reviewers identified 4 studies (N=461 patients). In a pooled analysis, the overall diagnostic accuracy was significantly higher in the EBUS transbronchial biopsy (TBB) group than in the conventional TBB group (odds ratio, 2.21; 95% CI, 1.42 to 3.44; p <.001).

The ACCP has published 2 reviews.[1,2] The ACCP reviews indicated that, in general, most of the evidence comes from small retrospective or prospective studies, plus 2 randomized controlled trials (RCTs).

Tables 2 and 3 summarize the characteristics and results of systematic reviews assessing the clinical validity studies using EBUS to diagnose lung cancer.

Table 2. Characteristics of Systematic Reviews Assessing the Clinical Validity of Radial EBUS for Diagnosing Lung Cancer

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Han et al (2018)[8]	2000-2016	24	Patients with small PLs ≤3 cm	4249 (24 to 795)	Prospective, retrospective	NR
Ali et al (2017)[9]	2002-2016	57	Patients receiving R-EBUS for diagnosing PPLs	7872 lesions (20 to 815 lesions)	Prospective, retrospective	NR
Ye et al (2017)[10]	2004-2014	4	Patients with PPLs referred for diagnostic bronchoscopy or R-EBUS-guided bronchoscopy	461 (92 to 145)	Prospective, retrospective	NR

EBUS: endobronchial ultrasound; NR: not reported; PL: pulmonary lesion; PPL: peripheral pulmonary lesion; R-EBUS: radial endobronchial ultrasound.

Table 3. Results of Systematic Reviews Assessing of Radial EBUS for Diagnosing Lung Cancer

Study	Diagnostic Yield, %	Diagnostic Yield PLs ≤2 cm, %	Overall Complication Rate, %	Pneumothorax, n/N (%)
Han et al (2018)[8]				
EBUS	75	66	NR	10/815 (1.23)
95% CI	69 to 80	55 to 76		
Computed tomography	93	92		660/3434 (19.23)
95% CI	90 to 96	88 to 95		
Ali et al (2017)[9]				
EBUS	70.6	60.5	2.8	NR
95% CI	68 to 73.1	56.6 to 64.4		
Ye et al (2017)[10]				
Odds ratio	2.183	5.045	NR	NR
95% CI	1.368 to 3.485	2.063 to 12.337		
p	.001	<.001		

CI: confidence interval; EBUS: endobronchial ultrasound; NR: not reported; PL: pulmonary lesion.

Randomized Controlled Trials

Two small randomized trials were identified that evaluated EBUS: one compared its use with TBB and the other, with conventional fluoroscopy-guided flexible bronchoscopy. An RCT by Fielding et al (2012) aimed to determine the diagnostic, complication, and patient tolerability rates of EBUS with a guide sheath EBUS and CT-guided percutaneous core biopsy for peripheral lung lesions among patients with visible lesions suspicious of malignancy.[11] Patients with lesions greater than 1 cm diameter on CT were randomized to guide sheath EBUS biopsy or CT-guided biopsy. Diagnostic sensitivity was 67% (22/33 cases) for guide sheath EBUS biopsy and 78% (19/24 cases) for CT-guided biopsy (p >.1). In those with negative results, 9 patients in the EBUS group had a CT-guided biopsy as a crossover, 7 of which were diagnostic. In the CT group, 4 had crossover EBUS biopsy, 3 of which were diagnostic. When both initial and crossover procedures were evaluated, sensitivity for malignancy was 17 (74%) of 23 for EBUS biopsy and 23 (88%) of 26 for CT-guided biopsy (p >.1). For

lesions less than 2 cm, a CT-guided biopsy had a significantly better diagnostic yield (80% vs. 50%, p=.05). In EBUS biopsy cases, for lesions with an air bronchogram, sensitivity was 89%. Pneumothorax and intercostal catheter insertion were performed in 3 and 2 cases, respectively, for EBUS, and 10 and 3 cases for CT-guided biopsy (p=.02 for pneumothorax). Nine unexpected admissions occurred after CT-guided biopsy compared with 3 after guide sheath EBUS biopsy.

In the RCT by Paone et al (2005), patients with identified peripheral lung lesions suspicious as malignancy who could undergo a complete clinical diagnostic follow-up (N=293) were enrolled in the trial and randomized to EBUS-TBB or TBB.[12,] Lung cancer was diagnosed in 61 patients in the EBUS-TBB group and in 83 patients in the TBB group. The sensitivity of EBUS (78.7%) was significantly higher than TBB (55.4%; p=.004). The specificity was 100% in both groups. Overall, the accuracy was 85% in the EBUS group and 69% in the TBB group (p=.007). The analysis of a subset of patients with lesions greater than 3 cm showed no significant difference in diagnostic ability between the 2 procedures. A considerable decline in TBB sensitivity (31%) and accuracy (50%; p=.0002) was observed in lesions less than 3 cm, while EBUS-TBB sensitivity (75%) and diagnostic yield (83%; p=.001) were maintained. A similar difference was observed when the sensitivity of the 2 procedures was compared in lesions less than 2 cm (23% vs. 71%, p<.001).

Tables 4 and 5 summarize the characteristics and results of RCTs assessing the clinical validity studies using EBUS to diagnose lung cancer.

Table 4. Characteristics of RCTs Assessing the Clinical Validity of EBUS for Diagnosing Lung Cancer

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Fielding et al (2012)[11,]	Australia	1	2007-2011	Patients with PPLs greater than 1 cm	EBUS-GS (n=33)	CT-guided biopsy (n=31)
Paone et al (2005)[12,]	Italy	1	2001-2003	Patients with PPLs	EBUS-TBB (n=87)	TBB (n=119)

CT: computed tomography; EBUS: endobronchial ultrasound; EBUS-GS: EBUS-guide sheath; EBUS-TBB: endobronchial ultrasound-driven transbronchial biopsy; PPL: peripheral pulmonary lesion; RCT: randomized controlled trial; TBB: transbronchial biopsy.

Table 5. Results of RCTs Assessing the Clinical Validity of EBUS for Diagnosing Lung Cancer

Study	Sens, %	Spec, %	Acc, %	Sensitivity for PPLs less than 2 cm, %	Sensitivity for PLLs less than 3 cm, %	Diagnostic Yield for PPLs less than 2 cm, %	Pneumothorax, n (%)
Fielding et al (2012)[11,]							
EBUS-GS	74	NR	NR	NR	NR	50	3 (8.1)
CT-guided biopsy	88					80	10 (30.3)
p	NR					.05	.02
Paone et al (2005)[12,]							
EBUS-TBB	78.7	100	85	71	75	NR	NR
TBB	55.4	100	69	23.3	30.7		
p	.004	NR	.007	<.001	.001		

Acc: accuracy; CT: computed tomography; EBUS: endobronchial ultrasound; EBUS-GS: guide sheath endobronchial ultrasound; EBUS-TBB: endobronchial ultrasound-driven transbronchial biopsy; NR=not reported; PPL: peripheral pulmonary lesion; RCT: randomized controlled trial; Sens: sensitivity; Spec: specificity; TBB: transbronchial biopsy.

The purpose of the limitations tables (see Tables 6 and 7) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Fielding et al (2012)[11,]					1. Follow-up duration not clear; perhaps 1 to 3 days
Paone et al (2005)[12,]				5. Complications (e.g., pneumothorax, chest tube insertions) not reported	1. Follow-up duration not reported

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.
[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.
[d] Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported;
5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).
[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true-positives, true-negatives, false-positives, false-negatives cannot be determined).

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Fielding et al (2012)[11,]	1. Unclear if allocation was concealed from patients	1. No blinding was performed		2. 7/64 (10.9%) did not complete the study		
Paone et al (2005)[12,]	1. Unclear if allocation was concealed from patients	1. Physicians performing procedures could not be blinded		2. 15/221 (6.8%) patients lost to follow-up and others unavailable, making treatment groups uneven (87 vs. 119)		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (ie, convenience).
[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.
[c]Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.
[d] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.
[f] Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison with other tests not reported.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs or other controlled studies reporting on longer-term health outcomes (i.e., mortality) were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

A chain of evidence for the clinical utility of EBUS-TBNA as an adjunct to standard bronchoscopy for the diagnosis of lung cancer is based on an examination of the data on diagnostic accuracy and an examination of harms associated with various diagnostic methods.

The available evidence supports a conclusion that EBUS-TBNA has diagnostic performance characteristics for solitary pulmonary lesions similar to those of traditional flexible bronchoscopic techniques with a transthoracic needle biopsy. The evidence also indicates the safety profile of EBUS-TBNA may be less risky than other techniques, as reflected by pneumothorax and chest tube insertion rates. For example, as found by Fielding et al (2012; discussed above), although CT-guided biopsy had higher yields in lesions less than 2 cm, EBUS-GS had better tolerability and fewer complications.[11,] The evidence does not establish that one technique is better than the others. Thus, the chain of evidence suggests that EBUS-TBNA can improve the net health outcome (i.e., has a similar benefit to alternative techniques with less harm).

Section Summary: Diagnosis of Lung Cancer

Evidence from 3 meta-analyses and 2 RCTs supports a conclusion that EBUS-TBNA has diagnostic performance characteristics for solitary pulmonary lesions similar to those of traditional flexible bronchoscopic techniques with a transthoracic needle biopsy. The available evidence also indicates the safety profile of EBUS-TBNA may be better than other techniques (e.g., CT-guided biopsy). This evidence does not establish that any technique is better than the others. The choice of technique for biopsy depends on a number of factors, including the size and location of the lesion(s) and the risks of the planned procedure.

Staging of Lung Cancer

Clinical Context and Test Purpose

The purpose of EBUS-TBNA in individuals who have lung cancer is to biopsy the lesions in order to stage the disease.

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

Populations

The relevant population of interest is individuals with lung cancer and mediastinal lymph nodes seen on imaging.

Interventions

The intervention of interest is EBUS-TBNA.

Comparators

Because EBUS is intended as an enhancement to standard bronchoscopic techniques, the primary comparator is flexible bronchoscopy with TBNA. Other methods for staging lung cancer includes positron emission tomography, transthoracic needle aspiration using CT guidance, and mediastinoscopy.

Outcomes
Outcomes of interest for diagnostic accuracy include test accuracy, test validity (e.g., sensitivity, specificity) and morbidity (e.g., pneumothorax and chest tube insertion rates). The primary outcomes of interest for clinical utility are overall survival and disease-specific survival.

An EBUS-TBNA would be performed after lung cancer is diagnosed.

Study Selection Criteria
For the evaluation of clinical validity of EBUS for lung cancer staging, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews
Appendix Table 2 provides a crosswalk of studies included in select reviews.El-Osta et al (2018) published a meta-analysis evaluating EBUS-TBNA for nodal staging of non-small-cell lung cancer with radiologically normal mediastinum.[13,] Thirteen studies were included, with a total of 1905 patients (range, 57 to 258 patients). Sensitivity was 49.5%, negative predictive value was 93.0%, and the diagnostic odds ratio was 5.069. The meta-analysis was limited by (1) major heterogeneity across included studies, (2) publication bias, (3) a lack of essential data in some studies, and (4) lack of consideration for size, location, and histology of tumor due to inconsistent reporting.

A systematic review, published by Ge et al (2015), compared EBUS-TBNA with mediastinoscopy for the mediastinal staging of lung cancer.[14,] Due to the extremely low rate of false-positive results, reviewers assumed that all positive results were true-positives. Thus, they only pooled analyses of sensitivity (with no false-positives, the specificity would be 100%). For the EBUS-TBNA studies, the pooled sensitivity was 83%; for mediastinoscopy, it was 86%. The difference in sensitivity was not statistically significant (p=.632). Seventeen complications, including 2 pneumothoraces, 2 cases of perioperative bleeding, 1 esophagus injury, and 1 wound infection, occurred in the mediastinoscopy group, and only 4 minor injuries occurred in the EBUS-TBNA group. A limitation of the literature selected for the systematic review is that studies were not head-to-head comparisons of staging techniques.

Tables 8 and 9 summarize the characteristics and results of systematic reviews assessing the clinical validity studies using EBUS to stage lung cancer.

Table 8. Characteristics of Systematic Reviews Assessing the Clinical Validity of EBUS-TBNA for Staging Lung Cancer

Study	Dates	Trials	Participants	N (Range)	Design	Duration
El-Osta et al (2018)[13,]	2006-2017	13	Patients receiving EBUS-TBNA to detect NSCLC with no radiologic mediastinal involvement	1905 (57 to 258)	Prospective, retrospective	NR
Ge et al (2015)[14,]	2003-2014	16	Patients with suspected or confirmed lung cancer	1914 (18 to 216)	Prospective, retrospective	NR

EBUS-TBNA: endobronchial ultrasound-guided transbronchial needle aspiration; NR: not reported; NSCLC: non-small-cell lung cancer.

Table 9. Results of Systematic Reviews Assessing the Clinical Validity of EBUS-TBNA for Staging Lung Cancer

Study	Sensitivity, %	Complications, n/N (%)	NPV, %	Diagnostic Odds Ratio
El-Osta et al (2018)[13,]				
EBUS-TBNA	49.5	NR	93.0	5.069
95% CI	36.4 to 62.6		90.3 to 95.0	4.212 to 5.925
Ge et al (2015)[14,]				
EBUS-TBNA	0.83	4/999 (0.4)	NR	NR
95% CI	0.79 to 0.87	NR		
Mediastinoscopy	0.86	17/915 (1.9)		
95% CI	0.82 to 0.90	NR		

CI: confidence interval; EBUS-TBNA: endobronchial ultrasound-guided transbronchial needle aspiration; NPV: negative predictive value; NR: not reported.

The ACCP published a systematic review, conducted by Silvestri et al (2013), with pooled analyses that provided a comprehensive resource for noninvasive and invasive methods to stage the mediastinum, including EBUS-based techniques.[3,] Table 10 summarizes the pooled test performance characteristics for a number of staging procedures drawn from the ACCP evidence review. The data in Table 10 would suggest the grouping of imaging techniques as a whole does not perform as well as the invasive techniques overall. Within the invasive grouping, there seems to be little apparent difference in terms of performance characteristics. Traditional surgical mediastinoscopy has long been considered the criterion standard for staging the mediastinum in patients diagnosed with lung cancer; variants of it are used in specific cases (e.g., when the cervical approach does not provide information specific to certain node stations). Mediastinoscopy is indicated mainly for patients who would be candidates for curative surgical resection. The less invasive guided needle-based methods are suitable for nonsurgical candidates or those who refuse surgery, yet require staging to plan specific systemic therapy or radiotherapy. They appear to have very similar performance characteristics based on the ACCP analyses, including EBUS-TBNA.

Table 10. Pooled Performance Characteristics of Techniques Used to Stage the Mediastinum in Patients With Lung Cancer[a]

Technique	N	Cancer Prevalence, %	Sens, %	Spec, %	PPV, %	NPV, %
CT with contrast enhancement	7368	30	55	81	58	83
PET alone	4105	28	80	88	75	91
PET-CT	2014	22	62	90	63	90
Traditional mediastinoscopy	9267	33	78	(100)[a]	(100)[a]	91
Video-assisted mediastinoscopy	995	31	89	(100)[a]	(100)[a]	92
Mediastinal lymphadenectomy	386	34	81	(100)[a]	(100)[a]	91
Video-assisted thoracic surgery	246	63	99	(100)[a]	(100)[a]	96
Transthoracic needle aspiration (percutaneous)	215	84	94	(100)[a]	(100)[a]	NR[b]
TBNA	2408	81	78	(100)[a]	(100)[a]	77
Esophageal EUS-guided needle aspiration	2443	58	89	(100)[a]	(100)[a]	86
Real-time EBUS-TBNA	2756	58	89	(100)[a]	(100)[a]	91

Adapted from Silvestri et al (2013).[3,]
CT: computed tomography; EBUS-TBNA: endobronchial ultrasound-guided transbronchial needle aspiration; EUS: endoscopic ultrasound; NPV: negative predictive value; NR: not reported; PET: positron emission tomography; PPV: positive predictive value; Sens: sensitivity; Spec: specificity; TBNA: transbronchial needle aspiration.
[a] Technically, the specificity and positive predictive value cannot be assessed in the studies reporting 100% values because a positive result was not followed by an additional criterion standard test.
[b] All patients had a mediastinal disease.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs or other controlled studies were identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

A chain of evidence of the clinical utility of EBUS-TBNA for the staging of lung cancer is based on an examination of the EBUS-TBNA data on diagnostic accuracy and harms associated with various staging techniques. The evidence underlying the pooled accuracy for mediastinal staging is less than optimal. The literature review for staging did not identify any RCT evidence to compare EBUS guidance with any other needle-based technique. There are differences among the patient populations and the use of reference standard confirmation of node positivity. The evidence summarized herein supports a conclusion that EBUS-TBNA exhibits test performance characteristics similar to other needle-based methods used to stage the mediastinum in patients diagnosed with lung cancer. Although EBUS-TBNA could be used in patients who are surgical candidates and plan to undergo surgery, it also may be suitable for those who are not eligible for curative resection or for those who refuse to undertake major surgery but still require staging for planning systemic or radiotherapy. A major advantage of EBUS-based methods is that they can be performed on an outpatient basis under limited sedation if necessary, and thus would be less invasive and less risky than traditional mediastinoscopy. Thus, the chain of evidence suggests that EBUS-TBNA may be more beneficial in certain situations

Section Summary: Staging of Lung Cancer
The literature review on the use of EBUS-TBNA for staging did not identify any RCT evidence that compared EBUS guidance with any other needle-based technique. The evidence summarized herein from systematic reviews supports a conclusion that EBUS-TBNA exhibits test performance characteristics similar to other needle-based methods used to stage the mediastinum in patients diagnosed with lung cancer. Although it could be used in patients who are surgical candidates and plan to undergo surgery, it also may be suitable for those who are not eligible for curative resection or refuse to undertake major surgery but still require staging for planning systemic or radiotherapy. A major advantage of EBUS-based methods is that they are less invasive and less risky than traditional mediastinoscopy.

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 College of Chest Physicians

The American College of Chest Physicians has offered a number of evidence-based guidelines on the use of endobronchial ultrasound (EBUS) -guided needle aspiration of pulmonary lesions for diagnosis of lung cancer[1,] and mediastinal staging of patients diagnosed with lung cancer (Table 11).[3,] A separate guideline and expert panel report (2016) has addressed the technical aspects of EBUS-guided transbronchial needle aspiration and its use outside the setting of lung cancer.[15,]

Table 11. Guidelines on Use of Endobronchial Ultrasound to Diagnose and Stage Lung Cancer

Recommendation	Grade
Diagnosis of peripheral pulmonary nodules	
"2.3.2. In patients suspected of having lung cancer, who have extensive infiltration of the mediastinum based on radiographic studies and no evidence of extrathoracic metastatic disease (negative PET scan), it is recommended that the diagnosis of lung cancer be established by the least invasive and safest method (bronchoscopy with TBNA, endobronchial ultrasound-guided needle aspiration [EBUS-NA], endoscopic ultrasound-guided needle aspiration [EUS-NA], transthoracic needle aspiration [TTNA], or mediastinoscopy)."	1C
"3.3.2.1. In patients suspected of having lung cancer, who have a peripheral lung nodule, and a tissue diagnosis is required due to uncertainty of diagnosis or poor surgical candidacy, radial EBUS is recommended as an adjunct imaging modality."	1C
Staging of the mediastinum in patients diagnosed with lung cancer	
"4.4.4.3. In patients with high suspicion of N2,3 involvement, either by discrete mediastinal lymph node enlargement or PET uptake (and no distant metastases), a needle technique (endobronchial ultrasound [EBUS]-needle aspiration [NA], EUS-NA or combined EBUS/EUS-NA) is recommended over surgical staging as a best first test....*Remark:* In cases where the clinical suspicion of mediastinal node involvement remains high after a negative result using a needle technique, surgical staging (e.g., mediastinoscopy, video-assisted thoracic surgery [VATS], etc) should be performed."	1B

EBUS: endobronchial ultrasound; PET: positron emission tomography; TBNA: transbronchial needle aspiration.

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on non-small-cell lung cancer (v 3.2023) [16,] state: "The least invasive biopsy with the highest yield is preferred as the first diagnostic study.... Patients with peripheral (outer one-third) nodules may benefit from navigational bronchoscopy, radial EBUS [endobronchial ultrasound], or transthoracic needle aspiration (TTNA).... Patients with suspected nodal disease should be biopsied by EBUS, EUS [endoscopic ultrasound], navigational bronchoscopy or mediastinoscopy."

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for endobronchial ultrasound have been identified.

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 ongoing trials that might influence this review are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02719847	Additive Value of EBUS TBNA for Staging Non-Small Cell Lung Cancer in Patients Evaluated for Stereotactic Body Radiation Therapy	150	Mar 2024
NCT04828850	Preoperative lymph node staging with EBUS-TBNA in clinical N0 non small-cell lung cancer	50	Dec 2022

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04852588	Endoscopic Nodal Staging in Oligometastatic Non-small Cell Lung Cancer (NSCLC) Being Treated With Stereotactic Ablative Radiotherapy (ENDO-SABR)	29	May 2023
Unpublished			
NCT00559611	Prospective Comparison of Endobronchial Ultrasound Needle Biopsy Versus Mediastinoscopy for Staging of Mediastinal Nodes in Patients With Clinical Stage IIIA Non-Small Cell Lung Cancer (NSCLC)	53	Mar 2018 (completed)

NCT: national clinical trial.

Appendix 1

Appendix Table 1. Crosswalk of Studies Included in Systematic Reviews Assessing the Clinical Validity of EBUS-TBNA for Diagnosing Lung Cancer

Study	Han et al (2018)[8]	Ye et al (2017)[10]
Sanchez-Font et al (2014)		●
Boonsarngsuk et al (2012)		●
Ishida et al (2012)		●
Shirakawa et al (2004)		●
Asahina et al (2005)	●	
Asano et al (2008)	●	
Ishida et al (2011)	●	
Oshige et al (2011)	●	
Tamiya et al (2013)	●	
Matsumoto et al (2015)	●	
Asano et al (2015)	●	
Oki et al (2015)	●	
Fukusumi et al (2016)	●	
Laurent et al (2000)	●	
Ohno et al (2003)	●	
Yamagami et al (2003)	●	
Yoshimatsu et al (2008)	●	
Hiraki et al (2009)	●	
Hwang et al (2010)	●	
Inoue et al (2012)	●	
Choi M.J. et al (2012)	●	
Choi J.W. et al (2012)	●	
Yamagami et al (2013)	●	
Lee et al (2014	●	
Yang et al (2015)	●	
Takeshita et al (2015)	●	
Jiao et al (2016)	●	
Rotolo et al (2016)	●	

EBUS-TBNA: endobronchial ultrasound-guided transbronchial needle aspiration.

Appendix Table 2. Crosswalk of Studies Included in Systematic Reviews Assessing the Clinical Validity of EBUS-TBNA for Staging Lung Cancer

Study	El-Osta et al (2018)[13]	Ge et al (2015)[14]
Kimura et al (2003)		●
Lardinois et al (2003)		●
Venissac et al (2003)		●
Yasufuku et al (2006)		●
Kimura et al (2007)		●
Lee et al (2008)		●
Hwangbo et al (2009)	●	●

Study	El-Osta et al (2018)[13]	Ge et al (2015)[14]
Anraku et al (2010)		●
Hwangbo et al (2010)		●
Sayar et al (2011)		●
Yasufuku et al (2011)		●
Lee et al (2012)	●	●
Zhang et al (2012)		●
Clementsen et al (2014)		●
Kang et al (2014)		●
Oki et al (2014)	●	●
Herth et al (2006)	●	
Herth et al (2008)	●	
Jamil et al (2009)	●	
Szlubowski et al (2010)	●	
Yasufuku et al (2013)	●	
Shingyoji et al (2014)	●	
Ong et al (2015)	●	
Edwards et al (2016)	●	
Taverner et al (2016)	●	
Naur et al (2017)	●	

EBUS-TBNA: endobronchial ultrasound-guided transbronchial needle aspiration.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Reason for endobronchial ultrasound-guided transbronchial needle aspiration
  - Treatment plan
- Prior imaging results

Post Service (in addition to the above, please include the following):

- Procedure report(s)

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®	31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures
	31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures
	31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for

Type	Code	Description
		peripheral lesion(s) (List separately in addition to code for primary procedure[s])
HCPCS	C7512	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with transendoscopic endobronchial ultrasound (ebus) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s), including fluoroscopic guidance when performed
	C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)

Policy History

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

Effective Date	Action
04/01/2016	BCBSA Medical Policy adoption
06/01/2017	Policy revision without position change
11/01/2017	Policy revision without position change
11/01/2018	Policy revision without position change
12/01/2019	Policy revision without position change
11/01/2023	Policy reactivated. Previously archived from 08/01/2020 to 10/31/2023.

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	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Reactivated Policy **Policy Statement:** N/A	**Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer 6.01.58** **Policy Statement:** I. Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) may be considered **medically necessary** for the evaluation of peripheral pulmonary lesions in individuals with suspected lung cancer when **all** of the following criteria are met: A. Tissue biopsy of the peripheral pulmonary lesion is required for diagnosis (see Policy Guidelines section); B. The peripheral pulmonary lesion is not accessible using standard bronchoscopic techniques. II. EBUS-TBNA is considered **medically necessary** for mediastinal staging in individuals with diagnosed lung cancer when **all** of the following criteria are met: A. The individual is suitable and willing to undergo specific treatment for lung cancer, with either curative or palliative intent (see Policy Guidelines section); B. Tissue biopsy of abnormal mediastinal lymph nodes seen on imaging is required for staging and specific treatment planning (see Policy Guidelines section); C. Abnormal lymph nodes seen on imaging are accessible by EBUS-TBNA. III. Endobronchial ultrasound is considered **investigational** for diagnosis and staging of lung cancer when the above criteria are not met. IV. Endobronchial ultrasound is considered **investigational** for all other indications.