PHP_7.01.122	Electromagnetic Navigational Bronchoscopy		
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State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

I. Electromagnetic navigation bronchoscopy (ENB) may be considered **medically necessary** when flexible bronchoscopy alone, or with endobronchial ultrasound, are considered inadequate to accomplish the diagnostic or interventional objective for **either** of the following:
   A. Establish a diagnosis of suspicious peripheral pulmonary lesion(s)
   B. Place fiducial markers within lung tumor(s) prior to treatment.

II. Electromagnetic navigation bronchoscopy is considered **investigational** for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not covered above.

Policy Guidelines

Bronchoscopists performing electromagnetic navigation bronchoscopy (ENB) require specific training in the procedure.

Enlarged mediastinal nodes were an early indication for ENB which has been largely replaced by endobronchial ultrasound. One could consider it in the uncommon scenario in which linear endobronchial ultrasound is not available and the individual is having an ENB procedure for a peripheral nodule in any case.

Coding

See the Codes table for details.

Description

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a 3-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs, so that suspicious lesions can be biopsied and to allow fiducial markers placement.

Summary of Evidence

For individuals who have suspicious peripheral pulmonary lesion(s) when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to sample the pulmonary lesion(s), the evidence includes meta-analyses, 2 randomized controlled trials (RCTs), and uncontrolled prospective observational studies. Relevant outcomes are test accuracy and validity, other test performance

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measures, and treatment-related morbidity. A 2023 meta-analysis of 55 studies, a 2020 meta-analysis of 40 studies, and a 2015 meta-analysis of 17 studies of electromagnetic navigation bronchoscopy (ENB) reported a large pooled positive likelihood ratio but a small negative likelihood ratio. Similarly, a 2014 meta-analysis of 15 studies found that navigation success was high, but diagnostic yield (64.9; 95% confidence interval [CI], 59.2 to 70.3) and negative predictive value (52.1; 95% CI, 43.5 to 60.6) were relatively low. In a 2024 meta-analysis of 363 studies (of which 94 assessed ENB), the diagnostic yield for ENB was 72.7%, which did not significantly differ when compared to other bronchoscopic procedures. The systematic reviews assessed the methodological quality of the evidence as low. In a 2025 multicenter RCT of 234 patients with intermediate-to-high-risk pulmonary nodules, ENB was noninferior to transthoracic needle biopsy in diagnostic accuracy (79% vs. 74%) and had markedly fewer complications (5.0% vs. 29.2%). Results from 2 large prospective multicenter uncontrolled studies, AQuiRE (American College of Chest Physicians Quality Improvement Registry, Evaluation, and Education) and NAVIGATE (Clinical Evaluation of superDimension Navigation System for Electromagnetic Navigation Bronchoscopy), provide information about test characteristics and safety of ENB. An analysis of more than 500 patients included in the AQuiRE registry found a diagnostic yield of ENB that was lower than in other studies, and lower than bronchoscopy without ENB or endobronchial ultrasound. In the US cohort of the NAVIGATE study, the 2-year diagnostic yield was 69.8%. Overall, 4.3% of patients experienced pneumothorax, and grade 2 or higher pneumothorax occurred in 2.9% of patients. Bronchopulmonary hemorrhage occurred in 2.5% of patients overall, and grade 2 or higher bronchopulmonary hemorrhage in 1.6% of patients. There were no deaths related to the ENB device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have enlarged mediastinal lymph nodes who receive ENB with flexible bronchoscopy, the evidence includes a RCT and case series. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. There is less published literature on ENB for diagnosing mediastinal lymph nodes than for diagnosing pulmonary lesions. One RCT found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration than with conventional transbronchial needle aspiration. Endobronchial ultrasound, which has been shown to be superior to conventional transbronchial needle aspiration, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to place the markers near the pulmonary lesion(s), the evidence includes 1 comparative observational study and several noncomparative observational studies and case series. Relevant outcomes are health status measures and treatment-related morbidity. In the largest series, a subgroup analysis of 258 patients from the NAVIGATE study, the subjective assessment of outcome was that 99.2% of markers were accurately placed and 94.1% were retained at follow-up (mean 8.1 days postprocedure). Pneumothorax of any grade occurred in 5.4% of patients, and grade 2 or higher pneumothorax occurred in 3.1%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2019 Input

Clinical input was sought to help determine whether the use of ENB with flexible bronchoscopy for individuals with suspicious peripheral pulmonary lesion(s), for individuals with enlarged mediastinal lymph node(s), and for individuals with lung tumor(s) who need fiducial marker placement prior to treatment would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 specialty society respondents offering a combined society-level response on

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behalf of both organizations, including input from physicians with academic medical center affiliations.

For individuals who have suspicious peripheral pulmonary lesion(s) who receive ENB with flexible bronchoscopy, clinical input supports this use and provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients. Clinical input states that ENB is generally reserved for the most difficult patients, who are poor or borderline candidates for surgery and transthoracic sampling. In this context, the "low yield" observed in observational studies was actually high for this highly selected population. ENB, when used as an option in the armamentarium of the bronchoscopist, is a highly useful and low-risk modality for proper diagnosis and staging of lung cancer. For example, patients who are able to achieve a positive biopsy result through ENB benefit by getting a diagnostic result to appropriately guide treatment while avoiding transthoracic needle biopsy which has a 2 to 4 times higher risk of pneumothorax than a bronchoscopic biopsy approach.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Clinical input states that mediastinal lymph node diagnosis was an early indication for ENB, which has been largely replaced by endobronchial ultrasound. One could consider it in the uncommon scenario in which linear endobronchial ultrasound is not available and the patient is already having an ENB procedure for a peripheral nodule.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, clinical input supports this use and provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients. Clinical input states that the key advantage of ENB placement is the markedly reduced risk of pneumothorax compared to the transthoracic approach. Patients being treated with targeted radiation are typically those with advanced respiratory disease who cannot undergo surgical resection. They are also more at risk for pneumothorax and resultant further complications. As the markers need to be near and not necessarily in a lesion, the accuracy advantage of a transthoracic approach is outweighed by the safety advantage of ENB over a transthoracic approach.

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

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Regulatory Status

In 2004, the superDimension/Bronchus™ inReach™ system (superDimension) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The system includes planning and navigation software, a disposable extended working channel, and a disposable steerable guide. The FDA cleared indication is for displaying images of the tracheobronchial tree that aids physicians in guiding endoscopic tools in the pulmonary tract. The device is not intended as an endoscopic tool; it does not make a diagnosis; and it is not approved for pediatric use. As of June 2016, the current version of the product is the Medtronic SuperDimension Navigation System (Medtronic). In 2019, a modified system, ILLUMISITE™ Platform, was also approved. The primary difference between the SuperDimension Navigation System and the ILLUMISITE Platform is the ability of the ILLUMISITE Platform to provide continuous positional feedback throughout the procedure (i.e. continuous guidance) via a sensor in the extended working channel. The system console hardware, software, and extended working channel were modified to incorporate the continuous guidance navigation feature.

In 2009, the ig4™ EndoBronchial system (Veran Medical) was cleared for marketing by the FDA through the 510(k) process. The system was considered to be substantially equivalent to the inReach system and is marketed as the SPiN Thoracic Navigation System™.

In April 2018, LungVision (Body Vision Medical) was cleared for marketing by the FDA through the 510(k) process (K172955). The FDA determined that this device was substantially equivalent to existing devices for use "segment previously acquired 3D CT [computed tomography] datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedure". FDA product code: EOQ.

Several other navigation software-only systems have been cleared for marketing by the FDA through the 510(k) process. They include:

- In 2008, the LungPoint® virtual bronchoscopic navigation (VPN) system (Broncus Technologies).
- In 2010, the bf-NAVI VPN system (Emergo Group).

FDA product codes: JAK, LLZ.

Two ENB systems are currently available, the SPiN Thoracic Navigation System (Veran Medical Technologies) and the superDimension™ navigation system (Medtronic).

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

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Rationale

Background

Pulmonary Nodules

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography scans. Although most nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when it is diagnosed later.

Diagnosis

Lung cancer is the leading cause of cancer-related death in the U.S., with an estimated 226,650 new cases and 124,730 deaths due to the disease in 2025.[1] The stage at which lung cancer is diagnosed has the greatest impact on prognosis. Localized disease confined to the primary site has a 64.7% relative 5-year survival, but accounts for only 25% of lung cancer cases at diagnosis.[2] Mortality increases sharply with advancing stage and metastatic lung cancer has a relative 5-year survival of 9.7%.[1] In addition to tumor stage, other factors such as age, sex, race/ethnicity, and performance status are independent prognostic factors for survival in patients with lung cancer.[1] The average age at diagnosis is about 70 years and most people diagnosed with lung cancer are 65 years of age or older. The lifetime risk of lung cancer is approximately 1 in 17 for men and 1 in 18 for women, with an increased risk in people who smoke. Rates of lung cancer have been dropping among men over the past few decades, but only for about the last decade in women.[2] Black men are about 12% more likely to develop lung cancer compared to White men, although Black men are less likely to develop small cell lung cancer when compared to White men.[1] Among women, the rate of lung cancer is about 16% lower for Black versus White women.

The method used to diagnose lung cancer depends on a number of factors, including lesion size, shape, location, as well as the clinical history and status of the patient. Peripheral lung lesions and solitary pulmonary nodules (most often defined as asymptomatic nodules <6 mm) are more difficult to evaluate than larger, centrally located lesions. There are several options for diagnosing malignant disease but none of the methods are ideal. Sputum cytology is the least invasive approach. Reported sensitivity rates are relatively low and vary widely across studies; sensitivity is lower for peripheral lesions. Sputum cytology, however, has a high specificity; and a positive test may obviate the need for more invasive testing. Flexible bronchoscopy, a minimally invasive procedure, is an established approach to evaluate pulmonary nodules. The sensitivity of flexible bronchoscopy for diagnosing bronchogenic carcinoma has been estimated at 88% for central lesions and 78% for peripheral lesions. For small peripheral lesions (<1.5 cm in diameter), the sensitivity may be as low as 10%. The diagnostic accuracy of transthoracic needle aspiration for solitary pulmonary nodules tends to be higher than that of bronchoscopy; the sensitivity and specificity are both approximately 94%. A disadvantage of transthoracic needle aspiration is that a pneumothorax develops in 11% to 25% of patients, and 5% to 14% require insertion of a chest tube. Positron emission tomography scans are also highly sensitive for evaluating pulmonary nodules yet may miss lesions less than 1 cm in size. A lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure.[3,4,5]

Advances in technology may increase the yield of established diagnostic methods. Computed tomography scanning equipment can be used to guide bronchoscopy and bronchoscopic transbronchial needle biopsy but have the disadvantage of exposing the patient and staff to radiation. Endobronchial ultrasound by radial probes, previously used in the perioperative staging of lung cancer, can also be used to locate and guide sampling of peripheral lesions. Endobronchial ultrasound is reported to increase the diagnostic yield of flexible bronchoscopy to at least 82%, regardless of lesion size or location.[3]

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Marker Placement

Another proposed enhancement to standard bronchoscopy is electromagnetic navigation bronchoscopy (ENB). Electromagnetic navigation bronchoscopy enhances standard bronchoscopy by providing a 3-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs. Once the navigation catheter is in place, any endoscopic tool can be inserted through the channel in the catheter to the target. This includes insertion of transbronchial forceps to biopsy the lesion. Also, the guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guidewire inserted through the catheter.

Literature Review

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.

Electromagnetic Navigation Bronchoscopy to Aid Diagnosing Pulmonary Lesions

Clinical Context and Test Purpose

The purpose of using electromagnetic navigation bronchoscopy (ENB) with flexible bronchoscopy in individuals who have suspicious peripheral pulmonary lesions is to confirm a diagnosis of lung cancer and to initiate treatment.

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

Populations

The relevant population of interest is individuals with suspicious peripheral pulmonary lesions.

Interventions

The test being considered is ENB with flexible bronchoscopy.

Comparators

The following tests are currently being used: flexible bronchoscopy only, computed tomography (CT)-guided needle biopsy and endobronchial ultrasound with flexible bronchoscopy.

Outcomes

The general outcomes of interest are the accurate identification of cancerous lesions and a reduction in disease-related morbidity and mortality. Potentially harmful outcomes are those resulting from false-positive or false-negative test results. False-positive test results can lead to unnecessary treatment. False-negative test results can lead to failure to initiate therapy. Potential procedure-related adverse events include pneumothorax, bronchopulmonary hemorrhage, and respiratory complications.

The time frame for evaluating the performance of the test varies from the time from the initial CT scan to an invasive diagnostic procedure to up to 2 years, which would be the typical follow-up needed for some lung nodules.

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Study Selection Criteria

For the evaluation of clinical validity of the ENB with flexible bronchoscopy, 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.

Several studies were excluded from the evaluation of the clinical validity because they did not use the marketed version of the test, did not include information needed to calculate performance characteristics, did not adequately describe the patient characteristics, or did not adequately describe patient selection criteria.

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).

Review of Evidence

Systematic Reviews

Balasubramanian et al (2024) published a meta-analysis evaluating the diagnostic yield and safety of ENB, radial endobronchial ultrasound, virtual bronchoscopy, robot-assisted bronchoscopy, and CT-guided transthoracic biopsy or needle aspiration for diagnosing peripheral pulmonary lesions.[6] The analysis included 363 studies in total, of which 94 assessed ENB (n=10,270 nodules). Radial endobronchial ultrasound studies accounted for the majority of studies included in the analysis (146 studies; n=28,383 nodules), whereas CT-guided transthoracic biopsy or needle aspiration studies, though fewer in number (80 studies), comprised the largest sample size of nodules (n=31,964).

Sun et al (2023) published a meta-analysis of the diagnostic value and safety of ENB for diagnosing peripheral pulmonary lesions suspected of cancer.[7] The analysis included 55 retrospective and prospective cohort studies (N=5,879). The authors reported that most of the literature included were deemed as unclear risk of bias because there were no suitable reference standards that were used across studies.

Folch et al (2020) published a systematic review of the literature on the sensitivity and safety of ENB for diagnosing peripheral pulmonary lesions suspected of cancer.[8] Forty prospective and retrospective studies (N=3,342) were included in the analysis. Many of the included studies were single-center, single-arm, and retrospective. Because most studies did not use a proper reference standard, the authors reported that most studies had a higher or unclear risk of bias regarding patient selection, index test, and the reference standard. Most studies used the superDimension system.

A systematic review of the literature on the diagnostic yield and safety of ENB was published by Zhang et al (2015).[9] Reviewers updated a systematic review by Gex et al (2014)[10] with newer studies. The Zhang et al (2015) review included prospective and retrospective studies of patients with peripheral nodules confirmed by a radiographic evaluation that had more than 10 patients and reported the diagnostic yield of ENB for peripheral lung nodules or lesions. Seventeen studies with 1161 lung nodules or lesions in 1106 patients met the eligibility criteria. Reviewers used the Quality Assessment of Diagnostic Accuracy Studies tool to evaluate the methodologic quality of selected studies, and overall quality was poor. None compared ENB with surgery, and, in almost all studies, reviewers reported it was uncertain whether the selected patients were representative of the population that would undergo ENB in an actual clinical setting.

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Results of pooled analyses are reported in Table 1. True-positive findings are those in which ENB biopsy yielded a definitive malignant diagnosis. True-negatives were defined as benign findings on ENB biopsy, confirmed by follow-up procedures. The Gex et al (2014) systematic review, which included 15 studies (N =971 patients), reported somewhat different outcomes (see Table 1).

Table 1. Meta-Analyses of Electromagnetic Navigation Bronchoscopy Performance

Outcomes	Rate (95% Confidence Interval), %	Rate (95% Confidence Interval), %	Rate (95% Confidence Interval), %	Rate (95% Confidence Interval), %	Rate (95% Confidence Interval), %
	Balasubramanian et al (2024)[6]	*Sun et al (2023)*[7]	*Folch et al (2020)*[8]	*Zhang et al (2015)*[9]	*Gex et al (2014)*[10]
Sensitivity for malignancy		0.77 (0.73 to 0.81)	77 (72 to 78) using random effects model; 76 (74 to 78) using fixed effect model	82 (79 to 85)	71.1 (64.6 to 76.8)
Specificity for malignancy		0.97 (0.93 to 0.99)	100 (99 to 100)	100 (98 to 100)	
Positive likelihood ratio		24.27 (10.21 to 57.67)	15.8 (10.3 to 24.2)	18.67 (9.04 to 38.55)	
Negative likelihood ratio		0.23 (0.19 to 0.28)	0.2 (0.1 to 0.3)	0.22 (0.15 to 0.32)	
Diagnostic odds ratio		104.19 (41.85 to 259.37)		97.36 (43.75 to 216.69)	
Navigation success					97.4 (95.4 to 98.5)
Diagnostic yield	• ENB: 72.7 (69.4 to 75.6) • Radial endobronchial ultrasound: 72.0 (70.1 to 73.8) • Virtual bronchoscopy: 75.1 (72.2 to 77.8) • CT-guided transthoracic biopsy or needle aspiration: 88.9 (87 to 90.5) • Robot-assisted bronchoscopy: 84.8 (81.1 to 87.88)				64.9 (59.2 to 70.3)
Accuracy for malignancy					78.6 (72.8 to 83.4)
Negative predictive value					52.1 (43.5 to 60.6)
Negative predictive value of intermediate benign results					78.5 (53.1 to 92.1)

ENB: electromagnetic navigation bronchoscopy;

As reported by Gex et al (2014), whereas the navigation success rate using ENB was generally very high, the diagnostic yield and negative predictive value (NPV) were relatively low.[10] Moreover, in Sun et al (2023), Folch et al (2020) and Zhang et al (2015), the positive likelihood ratio was large, but the negative likelihood ratio suggested only a small decrease in the likelihood of disease following the test.[7,8,9] Neither Sun, Folch, or Zhang conducted a pooled analysis of diagnostic yield. As stated at the beginning of this section, the evidence of particular interest is whether the test can correctly identify patients who do not have malignancy (i.e., high NPV or low negative likelihood ratio). Studies included in these 3 meta-analyses were limited because the surgical biopsy was not used as the criterion standard; it is unclear whether follow-up was long enough to confirm ENB diagnoses. Balasubramanian et al (2024) was the only meta-analysis to compare diagnostic yield between ENB and other bronchoscopic procedures.[6] The highest diagnostic yield was observed with CT-guided transthoracic biopsy or needle aspiration (88.9%), followed by robot-assisted bronchoscopy (84.8%), virtual bronchoscopy (75.1%), ENB (72.7%), and radial endobronchial ultrasound (72.0%). In a network meta-analysis, there were no statistically significant differences between ENB and any of the other modalities for diagnostic yield, based on low to very low certainty of evidence.

The pneumothorax rate following ENB was 3.27% in Sun et al (2023), 2% in Folch et al (2020), 5.9% in Zhang et al (2015), and 3.1% in Gex et al (2014) (1.6% required chest tube placement for pneumothorax).[9,10,8,7] Zhang et al (2015) stated that 2 of the pneumothoraxes were induced by transbronchial biopsy and the others were unrelated to the ENB procedure. Folch et al (2020) also reported a risk of major and minor bronchopulmonary bleeding of 0.8% and 1%, respectively, and a risk of acute respiratory failure of 0.6%.[8] Balasubramanian et al (2024) reported that pneumothorax, pneumothorax requiring a chest tube, and clinically significant bleeding occurred in 2.57%, 0.8%, and 0.8% of patients who received ENB, respectively.[6] The incidence of pneumothorax and pneumothorax requiring chest tube was highest with CT-guided transthoracic biopsy or needle aspiration (16.8% and 1.6%, respectively) and lowest with radial endobronchial ultrasound (0.9% and 0.2%, respectively). Clinically significant bleeding was greatest with CT-guided transthoracic biopsy or needle aspiration (5.2%) and least with robot-assisted bronchoscopy (0.3%).

Randomized Controlled Trials

Until recently, Eberhardt et al (2007) had published the only randomized controlled trial (RCT) to evaluate ENB for the diagnosis of pulmonary nodules.[11] This trial used surgical biopsy as a criterion standard confirmation of diagnosis. Patients were randomized to ENB only, endobronchial ultrasound only, or the combination of ENB and endobronchial ultrasound. Whereas ENB is designed to help navigate to the target but cannot visualize the lesion, endobronchial ultrasound is unable to guide navigation but enables direct visualization of the target lesion before the biopsy. The trial included 120 patients with evidence of peripheral lung lesions or solitary pulmonary nodules and who were candidates for elective bronchoscopy or surgery. In all 3 arms, only forceps biopsy specimens were taken, and fluoroscopy was not used to guide the biopsies. The primary outcome was the diagnostic yield, defined as the ability to yield a definitive diagnosis consistent with clinical presentation. If transbronchial lung biopsy did not provide a diagnosis, patients were referred for a surgical biopsy. The mean size of the lesions was 26 mm.

Two patients who did not receive a surgical biopsy were excluded from the final analysis. Of the remaining 118 patients, 85 (72%) had a diagnostic result via bronchoscopy, and 33 required a surgical biopsy. The diagnostic yield by intervention group was 59% (23/39) with ENB only, 69% (27/39) with endobronchial ultrasound only, and 88% (35/40) with ENB plus endobronchial ultrasound; the yield was significantly higher in the combined group. The NPV for the malignant disease was 44% (10/23) with ENB only, 44% (7/16) with endobronchial ultrasound only, and 75% (9/12) with combined ENB and endobronchial ultrasound. Note that the number of cases was small, and thus the NPV is an imprecise estimate. Moreover, the trialists stated that the yield in the ENB only group was somewhat lower than in other studies; they attributed this to factors such as the use of forceps for biopsy (rather than forceps and endobronchial brushes, which would be considered standard) and/or an improved

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diagnosis using a criterion standard. The pneumothorax rate was 6%, which did not differ significantly across the 3 groups.

More recently, in 2025, Lentz et al published the VERITAS trial, a noninferiority RCT comparing ENB with transthoracic needle biopsy for the diagnosis of peripheral pulmonary nodules.[12] The trial enrolled 258 patients across 7 U.S. centers with intermediate-to-high-risk pulmonary nodules (10 to 30 mm diameter). Patients were randomized 1:1 to undergo either ENB or biopsy. The primary outcome was diagnostic accuracy, defined as a biopsy diagnosis (cancer or specific benign condition) confirmed during 12 months of clinical follow-up.

Of 234 evaluable patients, the diagnostic accuracy was 79.0% in the ENB group and 73.6% in the biopsy group, demonstrating noninferiority of ENB (absolute difference, 5.4 percentage points; 95% CI, -6.5 to 17.2; p=.003 for noninferiority).[12] The false-negative rate was 0% with ENB compared to 3.6% with biopsy. ENB was considered diagnostic, defined as yielding malignant or specific benign pathology, in 79.3% of cases vs. 77.9% for biopsy (difference, 1.5 percentage points; 95% CI, -9.9 to 12.8). Complications were significantly lower with ENB (5.0% vs. 29.2%; p<.001), primarily due to a reduced pneumothorax rate (3.3% vs. 28.3%; p<.001). Procedure time was longer with ENB (median, 36 vs. 25 minutes), and rapid onsite cytologic evaluation was more common (95.8% with ENB vs. 7.2% with biopsy; difference, 88.6%; 95% CI, 81.4 to 95.8).

Prospective Uncontrolled Studies

One key uncontrolled prospective, multicenter observational study is the NAVIGATE study. NAVIGATE is a prospective, multicenter (37 sites) analysis of outcomes in patients who received ENB in U.S. and European (EU) centers. The study has broad inclusion criteria, including all adults who were candidates for ENB based on physician discretion, guideline recommendations, and institutional protocol. Participating physicians needed to have previous experience with ENB. Analyses of 1-month data on the first 1000 patients and 12-month data from the U.S. cohort have been published.[13,14]

Khandhar et al (2017) published a preplanned 1-month interim analysis of the first 1000 patients from the NAVIGATE study.[13] The analysis focused on safety outcomes; the primary endpoint was pneumothorax. Most of the first 1000 patients (n=964 [96%]) had ENB for evaluation of lung lesions. Any grade pneumothorax occurred in 49 (4.9%) of 1000 patients and pneumothorax of grade 2 or higher occurred in 32 (3.2%) patients. The rate of bronchopulmonary hemorrhage was 2.3%. There were 23 deaths by the 1-month follow-up, none was considered related to the ENB device but 1 was deemed related to general anesthesia complications.

Folch et al (2019) published 1-year results from the U.S. cohort of NAVIGATE (1215 patients at 29 sites).[14] This analysis included diagnostic outcomes as well as adverse events. Twelve-month follow-up was completed in 976 of 1215 (80.3%) patients. Navigation was successful and tissue was obtained in 1092 of the 1157 patients who received ENB for lung lesion biopsy (94.4%). Of these 1092 biopsies, 44.3% diagnosed malignancy (484) and 55.7% (608) were negative. As of 12 months, 284 initially negative outcomes were considered true-negative and 220 were false-negative. The 12-month diagnostic yield was 72.9% and ranged from 66.4% to 75.4%, assuming all deferred cases were false-negatives and true-negatives, respectively.

Most adverse events occurred within the first-month post-procedure and were previously reported in Khandar et al (2017). Overall, 4.3% of the patients had experienced pneumothorax. Pneumothorax requiring hospitalization or intervention (Common Terminology Criteria for Adverse Events [CTCAE] grade 2 or higher) occurred in 35 of 1215 patients (2.9%). Bronchopulmonary hemorrhage occurred in 2.5% of patients overall and CTCAE grade 2 or higher in 1.5%. Grade 4 or higher respiratory failure occurred in 0.7% of patients. There were 23 deaths at 12 months, none related to the ENB device. There was 1 anesthesia-related death 9 days post-procedure in a patient with multiple comorbidities.

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Folch et al (2022) published 2-year results from the EU and U.S. cohorts of NAVIGATE (1388 patients at 37 sites).[15] The 2-year mortality rate was 29% (403 of 1388 patients). Any-grade pneumothorax occurred in 4.7% of participants (7.4% EU; 4.3% U.S.), and grade 2 or higher pneumothorax occurred in 3.2% of participants (5.1% EU; 2.9% U.S.). The rate of any-grade bronchopulmonary hemorrhage was 2.7% (4% EU; 2.5% U.S.), and the rate of grade 2 or higher bronchopulmonary hemorrhage was 1.7% (2.3% EU; 1.6% U.S.). Navigation was successful and tissue was obtained in 1260 of the 1329 patients who received ENB for lung lesion biopsy (94.8%). At 2 years, of the 723 cases initially considered negative for malignancy, 285 were true-negative, 321 were false-negative, and 117 remained indeterminate. The diagnostic yield was 67.8% (range not provided) in the global cohort, 55.2% (range: 52.3% to 57.5%) in the EU cohort, and 69.8% (range: 63.3% to 72.6%) in the U.S cohort. In the global, EU, and U.S. cohorts, sensitivity for malignancy was 62.6% (range: 55.1% to 62.6%), 44.7% (range: 41.7% to 44.7%), and 65.6% (range: 57.2% to 65.6%), whereas NPV was 47.0% (range: 39.4% to 55.6%), 34.6% (range: 31.9% to 39.8%), and 49.6% (range: 40.8% to 58.5%), respectively. In a univariate analysis of the global cohort, Hispanic or Latino ethnicity was associated with lower diagnostic yield (63%: range: 41% to 98%).

Key uncontrolled observational studies not included in the meta-analyses are described next, focusing on prospective multicenter studies.

The American College of Chest Physicians has established a registry of bronchoscopies performed for the diagnosis of peripheral lung nodules or masses to evaluate the diagnostic yield of different approaches in clinical practice, which may differ from findings in the clinical trial setting. Data from this registry, called AQuiRE (American College of Chest Physicians Quality Improvement Registry, Evaluation, and Education), were published by Ost et al (2016).[16] The primary outcome of this analysis was the diagnostic yield of bronchoscopy, defined as the ability to obtain a specific malignant or benign diagnosis. Bronchoscopy was diagnostic in 312 (53.7%) of 581 peripheral lesions. Diagnostic yield was 63.7% for bronchoscopy with no endobronchial ultrasound or ENB, 57.0% with endobronchial ultrasound alone, 38.5% with ENB alone, and 47.1% with ENB plus endobronchial ultrasound. ENB was reserved for the most difficult patients. They tended to be poor or borderline candidates for surgery and transthoracic sampling. The procedure was planned for ENB, whether or not eventually used, and ENB was done only when the other approaches were inadequate. In this context, the "low yield" observed for ENB was actually high for this highly selected population. Complications occurred in 13 (2.2%) of 591 patients. Pneumothorax occurred in 10 (1.7%) patients, 6 of whom required chest tubes. Pneumothorax rates were not reported for bronchoscopy with and without ENB. In AQuiRE, ENB was reserved for the most difficult patients.

One prospective observational study has examined the sequential use of ENB; endobronchial ultrasound was used initially, with the addition of ENB when endobronchial ultrasound failed to reach or diagnose the lesion.

A study by Chee et al (2013) included 60 patients with peripheral pulmonary lesions.[17] Patients either had a previous negative CT-guided biopsy or did not have 1 due to technical difficulties. An attempt was first made to identify the lesion using peripheral endobronchial ultrasound, and if not identified, then an ENB system was used. Nodules were identified by endobronchial ultrasound alone in 45 (75%) of 60 cases. ENB was used in 15 (25%) cases, and in 11 (73%) of these cases the lesion was identified. Peripheral endobronchial ultrasound led to a diagnosis in 26 cases and ENB in an additional 4 cases, for a total diagnostic yield of 30 (50%) of 60 cases. In this study, the extent of improved diagnosis with ENB over endobronchial ultrasound alone was not statistically significant (p=.125). The rate of pneumothorax was 8% (5/60 patients); the addition of ENB did not alter the pneumothorax rate.

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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, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary 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 were identified that evaluated health outcomes for the use of ENB.

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.

Because the clinical validity of ENB cannot be established, a chain of evidence cannot be constructed.

Section Summary: Electromagnetic Navigation Bronchoscopy to Aid Diagnosing Pulmonary Lesions
A 2023 meta-analysis of 55 studies, a 2020 meta-analysis of 40 studies, and a 2015 meta-analysis of 17 studies of ENB reported a large pooled positive likelihood ratio but a small negative likelihood ratio. Similarly, a 2014 meta-analysis of 15 studies found that navigation success was high, but diagnostic yield (64.9; 95% confidence interval [CI], 59.2 to 70.3) and NPV (52.1; 95% CI, 43.5 to 60.6) were relatively low. In a 2024 meta-analysis of 363 studies (of which 94 assessed ENB), the diagnostic yield for ENB was 72.7%, which did not significantly differ when compared to other bronchoscopic procedures. The systematic reviews assessed the methodological quality of the evidence as low. In a 2025 multicenter RCT of 234 patients with intermediate-to-high-risk pulmonary nodules, ENB was noninferior to transthoracic needle biopsy in diagnostic accuracy (79% vs. 74%) and had fewer complications (5.0% vs. 29.2%). Results from 2 large prospective multicenter uncontrolled studies, AQuiRE and NAVIGATE, provide information about test characteristics and safety of ENB. An analysis of more than 500 patients included in the AQuiRE registry found a diagnostic yield of ENB that was lower than in other studies, and lower than bronchoscopy without ENB or endobronchial ultrasound. In the U.S. cohort of the NAVIGATE study, the 2-year diagnostic yield was 69.8%. Overall, 4.3% of patients experienced pneumothorax, and grade 2 or higher pneumothorax occurred in 2.9% of patients. Bronchopulmonary hemorrhage occurred in 2.5% of patients overall, and grade 2 or higher bronchopulmonary hemorrhage in 1.6% of patients. There were no deaths related to the ENB device.

Electromagnetic Navigation Bronchoscopy to Aid in the Diagnosis of Mediastinal Lymph Node(s)
Clinical Context and Test Purpose
The purpose of using ENB with flexible bronchoscopy in individuals who have enlarged mediastinal lymph nodes is to inform a decision whether to initiate treatment for lung cancer.

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

Populations
The relevant population of interest is individuals with enlarged mediastinal lymph nodes

Interventions
The test being considered is ENB with flexible bronchoscopy.

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Comparators

The following tests are currently being used: flexible bronchoscopy only, CT-guided needle biopsy, and endobronchial ultrasound with flexible bronchoscopy.

Outcomes

The general outcomes of interest are the accurate identification of mediastinal lymph nodes and reduction in disease-related morbidity and mortality. Potentially harmful outcomes are those resulting from false-positive or false-negative test results. False-positive test results can lead to unnecessary treatment. False-negative test results can lead to failure to initiate. Potential procedure-related adverse events include pneumothorax, bronchopulmonary hemorrhage, and respiratory complications. The time frame for outcome measures varies from short-term development of invasive procedure-related complications to long-term procedure-related complications, disease diagnosis, or overall survival.

Study Selection Criteria

For the evaluation of clinical validity of the ENB with flexible bronchoscopy, 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.

Several studies were excluded from the evaluation of the clinical validity because they did not use the marketed version of the test, did not include information needed to calculate performance characteristics, did not adequately describe the patient characteristics, or did not adequately describe patient selection criteria.

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).

Review of Evidence

Randomized Controlled Trials

One RCT was identified on ENB for the diagnosis of mediastinal lymph nodes The trial, reported by Diken et al (2015), included 94 patients with mediastinal lymphadenopathy with a short axis greater than 1 cm on CT and/or increased uptake on positron emission tomography.[18] Patients were randomized to conventional transbronchial needle aspiration (TBNA; n=50) or ENB-guided TBNA (n=44). All samples were evaluated by a blinded cytopathologist. Sampling success was defined as the presence of lymphoid tissue in the sample, and diagnostic success was the ability to make a diagnosis using the sample. Diagnoses were confirmed by 1 of several methods, such as mediastinoscopy, thoracotomy, or radiologic follow-up. Final diagnoses were sarcoidosis (n=29), tuberculous lymphadenitis (n=12), non-small-cell lung cancer (n=20), small-cell lung cancer (n=12), benign lymph node (n=5), and others (n=5). Sampling success was 82.7% in the ENB group and 51.6% in the conventional TBNA group (p<.001); diagnostic success was 72.8% in the ENB group and 42.2% in the conventional TBNA group (p<.001). When samples were stratified by mediastinal lymph node size, both sampling success and diagnostic success were significantly higher with ENB than with conventional TBNA in mediastinal lymph nodes 15 mm or less and more than 15 mm. The trialists noted that, although endobronchial ultrasound-guided TBNA has been shown to have higher diagnostic yields than conventional TBNA, endobronchial ultrasound was not compared with ENB because it was not available at the institution in Turkey conducting the study. No pneumothorax or other major adverse events were reported for either group.

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Case Series

No large uncontrolled studies were identified that focused on ENB for the diagnosis of mediastinal lymph nodes. A case series by Wilson et al (2007) included both patients with suspicious lung lesions and enlarged mediastinal lymph nodes.[19] There was no consistent protocol for confirming the diagnosis, although the authors stated that most patients were followed for confirmation of diagnosis. ENB was used to locate, register, and navigate to the lesions. Once navigation was completed, fluoroscopic guidance was used to verify its accuracy and to aid in the biopsy or TBNA. Sixty-seven (94%) of 71 mediastinal lymph nodes were successfully reached, and tissue samples for biopsy were obtained from all of them. The primary study outcome was the diagnostic yield on the day of the procedure; this was obtained for 64 (96%) of 67 of the lymph nodes reached.

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, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary 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 were identified that evaluated health outcomes for the use of ENB.

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.

Because the clinical validity of ENB cannot be established, a chain of evidence cannot be constructed.

Section Summary: Electromagnetic Navigation Bronchoscopy to Aid in the Diagnosis of Mediastinal Lymph Node(s)

There is less published literature on ENB for diagnosing mediastinal lymph nodes than for diagnosing pulmonary lesions. One RCT found higher sampling and diagnostic success with ENB-guided TBNA than with conventional TBNA. Endobronchial ultrasound, which has been shown to be superior to conventional TBNA, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies.

Electromagnetic Navigation Bronchoscopy to Aid in Placement of Fiducial Markers Prior to Treatment

Clinical Context and Therapy Purpose

The purpose of using ENB with flexible bronchoscopy in individuals who have lung tumors requiring placement of fiducial markers when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to place the markers near the pulmonary lesion(s) 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 lung tumors requiring placement of fiducial markers prior to treatment when flexible bronchoscopy alone or with endobronchial ultrasound is inadequate to place the markers near the pulmonary lesion(s).

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Intervention
The intervention of interest is ENB with the placement of fiducial markers.

The purpose of ENB is to allow navigation to distal regions of the lungs. Once the navigation catheter is in place, any endoscopic tool can be inserted through the channel in the catheter to the target. The guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guidewire inserted through the catheter.

Comparators
The following practice is currently being used: placement of fiducial markers using CT or ultrasound guidance.

Outcomes
The general outcomes of interest are a reduction in surgical complications compared with other surgical techniques.

The time frame for outcome measures varies from short-term development of invasive procedure-related complications to long-term procedure-related complications, disease progression, or overall survival.

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
Evaluation of ENB as an aid to the placement of fiducial markers involves searching for evidence that there are better clinical outcomes when ENB is used to place markers than when fiducials are placed using another method or when no fiducial markers are used. This review only evaluates the use of ENB to place fiducial markers; it does not evaluate the role of fiducial markers in radiotherapy.

Comparative Observational Study
Only one study was identified that compared fiducial marker placement using ENB with another method of fiducial marker placement; it was not randomized. This study, by Kupelian et al (2007), included 28 patients scheduled for radiotherapy for early-stage lung cancer.[20] Follow-up data were available for 23 (82%) patients; 15 had markers placed transcutaneously under CT or fluoroscopic guidance, and 8 patients had markers placed transbronchially with ENB. At least 1 marker was placed successfully within or near a lung tumor in all patients. The fiducial markers did not show substantial migration during treatment with either method of marker placement. The only clinical outcome reported was the rate of pneumothorax; 8 of 15 patients with transcutaneous placement developed a pneumothorax, 6 of whom required chest tubes. In contrast, none of the 8 patients with transbronchial placement developed pneumothorax. This study had a small sample size and a substantial dropout rate.

Noncomparative Observational Studies and Case Series
Several noncomparative observational studies and case series were identified.[13,21,22,23,24,25,26] Studies with the largest sample sizes are described next.

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Two publications from the NAVIGATE observational cohort study (described above) have reported preliminary outcomes in patients who had fiducial marker placement with ENB.[13,27] In an interim analysis reported by Khandhar et al (2017), 210 patients received 417 fiducial markers.[13] The subjective operator assessment of accurate placement of the fiducial markers was 208 (99%) in the 210 patients and 192 (94%) of 205 fiducial markers were retained at follow-up imaging. The timing of follow-up imaging was not specified. ENB-related adverse events included 8 (4%) cases of pneumothorax (grade ≥2), 3 cases of respiratory failure (grade ≥4), and a single bronchopulmonary hemorrhage (grade 1). Bowling et al (2019) reported 1-month outcomes in 258 patients who had a total of 563 fiducial markers placed at 21 centers in the U.S.[27] Follow-up data were available for 255/258 patients (99.8%). Based on subjective operator assessment, fiducial markers were accurately placed in 99.2% of patients (256/258). Follow-up imaging occurred an average of 8.1 days postprocedure and showed that 239 of 254 markers remained in place (239/254). Fourteen patients (5.4%) experienced pneumothorax; in 8 patients (3.1%) the pneumothorax was rated CTCAE grade 2 or higher.

Bolton et al (2015) retrospectively reported on ENB fiducial marker placement in 64 patients (68 lung lesions) for guiding stereotactic radiotherapy.[23] A total of 190 fiducial markers were placed, 133 in upper-lobe lesions and 57 markers in lower-lobe lesions. The rate of marker retention (the study's primary endpoint) was 156 (82%) of 190. Retention rate, by lobe, ranged from 68 (80%) of 85 in the right upper lobe to 10 (100%) of 10 in the right middle lobe. Complications included 3 (5%) unplanned hospital admissions, 2 cases of respiratory failure, and 2 cases of pneumothorax.

Schroeder et al (2010) reported findings from a prospective study with 52 patients who underwent placement of fiducial markers using ENB.[22] All patients had peripheral lung tumors; 47 patients had inoperable tumors and 5 patients refused surgery. Patients were scheduled to receive tumor ablation using the stereotactic radiosurgery, which involved fiducial marker placement. The procedures were considered successful if the markers remained in place without migration during the timeframe required for radiosurgery. A total of 234 fiducial markers were deployed. Radiosurgery planning CT scans were performed between 7 and 14 days after fiducial marker placement. The planning CT scans showed that 215 (99%) of 217 coil spring markers and 8 (47%) of 17 linear markers remained in place, indicating a high success rate for coil spring markers. Three patients developed pneumothorax; 2 were treated with chest tubes, and 1 received observation only.

An advantage of ENB is that it allows the placement of pleural dye and/or fiducial markers in the same procedure as ENB-guided lung lesion biopsy, thereby reducing the need for a second procedure and potentially reducing risks to the patient. For example, in NAVIGATE, all but 39 of the patients had lung lesion biopsy or pleural dye marking during the same procedure.[27] Patients being treated with targeted radiation are typically those with advanced respiratory disease who cannot undergo surgical resection. They are also more at risk for pneumothorax and resultant further complications. As the markers need to be near and not necessarily in a lesion, the accuracy advantage of a transthoracic approach is outweighed by the safety advantage of ENB over a transthoracic approach.

Section Summary: Electromagnetic Navigation Bronchoscopy to Aid in Placement of Fiducial Markers Prior to Treatment

There is only 1 study comparing ENB with another method of fiducial marker placement, and only 8 patients in that study who had markers placed with ENB had data available. There are several noncomparative observational studies and case series. In the largest series, a subgroup analysis of 258 patients from the NAVIGATE study, the subjective assessment of outcome was that 99.2% of markers were accurately placed and 94.1% were retained at follow-up (mean 8.1 days postprocedure). Pneumothorax of any grade occurred in 5.4%% of patients, and grade 2 or higher pneumothorax occurred in 3.1%.

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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.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2019 Input

Clinical input was sought to help determine whether the use of electromagnetic navigation bronchoscopy (ENB) with flexible bronchoscopy for individuals with suspicious peripheral pulmonary lesion(s), for individuals with enlarged mediastinal lymph node(s), and for individuals with lung tumor(s) who need fiducial marker placement prior to treatment would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 specialty society respondents offering a combined society-level response on behalf of both organizations, including input from physicians with academic medical center affiliations.

For individuals who have suspicious peripheral pulmonary lesion(s) who receive ENB with flexible bronchoscopy, clinical input supports this use and provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients. Clinical input states that ENB is generally reserved for the most difficult patients, who are poor or borderline candidates for surgery and transthoracic sampling. In this context, the "low yield" observed in observational studies was actually high for this highly selected population. ENB, when used as an option in the armamentarium of the bronchoscopist, is a highly useful and low-risk modality for proper diagnosis and staging of lung cancer. For example, patients who are able to achieve a positive biopsy result through ENB benefit by getting a diagnostic result to appropriately guide treatment while avoiding transthoracic needle biopsy, which has a 2 to 4 times higher risk of pneumothorax than a bronchoscopic biopsy approach.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Clinical input states that mediastinal lymph node diagnosis was an early indication for ENB, which has been largely replaced by endobronchial ultrasound. One could consider it in the uncommon scenario in which linear endobronchial ultrasound is not available and the patient is already having an ENB procedure for a peripheral nodule.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, clinical input supports this use and provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients. Clinical input states that the key advantage of ENB placement is the markedly reduced risk of pneumothorax compared to the transthoracic approach. Patients being treated with targeted radiation are typically those with advanced respiratory disease who cannot undergo surgical resection. They are also more at risk for pneumothorax and resultant further complications. As the markers need to be near and not necessarily in a lesion, the accuracy advantage of a transthoracic approach is outweighed by the safety advantage of ENB over a transthoracic approach.

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 U.S. professional society, an international society with U.S.

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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

In 2013, the American College of Chest Physicians updated its guidelines on the diagnosis of lung cancer.[28] Regarding ENB, the guidelines stated: "In patients with peripheral lung lesions difficult to reach with conventional bronchoscopy, electromagnetic navigation guidance is recommended if the equipment and the expertise are available." The College noted that the procedure can be performed with or without fluoroscopic guidance and has been found to complement radial probe ultrasound. The strength of evidence for this recommendation was grade 1C ("strong recommendation, low- or very-low-quality evidence").

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (v.3.2025) practice guidelines on non-small-cell lung cancer state that the strategy for diagnosing lung cancer should be individualized and the least invasive biopsy with the highest diagnostic yield is preferred as the initial diagnostic study.[29]

- "Patients with central masses and suspected endobronchial involvement should undergo bronchoscopy.
- Patients with pulmonary nodules may benefit from navigational bronchoscopy (including robotic), radial EBUS [endobronchial ultrasound], or transthoracic needle aspiration (TTNA).
- Patients with suspected nodal disease should be biopsied by EBUS, EUS [endoscopic ultrasound], navigation biopsy, or mediastinoscopy."

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

A search of ClinicalTrials.gov in April 2025 did not identify any ongoing or unpublished trials that would likely influence this review.

Appendix 1

2019 Clinical Input

Objective

Clinical input was sought to help determine whether the use of ENB with flexible bronchoscopy for individuals with suspicious peripheral pulmonary lesion(s), for individuals with enlarged mediastinal lymph node(s), and for individuals with lung tumor(s) who need fiducial marker placement prior to treatment would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 specialty society respondents offering a combined society-level response on behalf of both organizations, including input from physicians with academic medical center affiliations.

Respondents

Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- Combined response from American Thoracic Society (ATS) and American College of Chest Physicians (CHEST)

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by a specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a specialty society and/or physician member designated by a specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by Blue Cross Blue Shield Association (BCBSA) nor any Blue Plan.

Respondent Profile

	Specialty Society	
#	**Name of Organization**	**Clinical Specialty**
1	American Thoracic Society (ATS) and American College of Chest Physicians (CHEST)	Pulmonary, Critical Care, Sleep

Respondent Conflict of Interest Disclosure

#	Conflict of Interest Policy Statement
1	Response formulated by members of the Joint ATS/CHEST Clinical Practice Committee and submitted for the societies by the committee chairs. No relevant conflicts

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response. NR = not reported

Responses

- We are seeking your opinion on whether using the interventions for the below indications provide a clinically meaningful improvement in net health outcome. Please respond based on the evidence and your clinical experience. Please address these points in your response:
  - Relevant clinical scenarios (e.g., a chain of evidence) where the technology is expected to provide a clinically meaningful improvement in net health outcome;
  - Specific outcomes that are clinically meaningful;
  - Any relevant patient inclusion/exclusion criteria or clinical context important to consider in identifying individuals for this indication; and
  - Supporting evidence from the authoritative scientific literature (please include PMID).

#	Indications	Rationale
1	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with suspicious peripheral pulmonary lesion(s)	Suspicious Pulmonary Nodule. First, we wish to comment on the definition. A solitary pulmonary nodule is one of 3 cm or less in diameter, not 6 mm. The comparators used were standard flexible bronchoscopy, CT guided biopsy, and endobronchial ultrasound bronchoscopy. ENB is done by specially trained bronchoscopists who are well versed in a bronchoscopic procedures, including Endobronchial Ultrasound (EBUS) and ENB. This makes them best positioned to choose the most clinically appropriate option. While standard flexible bronchoscopy has a lower overall yield than ENB, the trained bronchoscopist can determine standard bronchoscopy is adequate for sampling and only use the more advanced technology for the more challenging cases. This also applies to the improved yield with radial probe ultrasound-guided sampling of peripheral nodules. The added step of ENB, is by definition, needed in the more difficult patient who cannot be accommodated by the plain or ultrasound-guided

#	Indications	Rationale
		bronchoscopy. In fact, the nonrandomized database studies actually demonstrate that with the selective use of ENB, the "low yield" is actually quite high for such a select patient population. As committee members participated in the AQuiRE database (1), we can speak to actual experience. ENB was reserved for the most difficult patients. They tended to be poor or borderline candidates for surgery and transthoracic sampling. The procedure was planned for ENB whether or not eventually used (Note: planning is neither billable or reimbursable) and ENB was done only when the other approaches were inadequate. Example: If the patient had suspicious lymph nodes and a suspicious nodule, convex probe (scope based) EBUS would be done first. If the diagnosis was made, no sampling of the nodule was required. If the lesion still needed sampling and was reachable by fluoroscopy or radial probe ultrasound, no ENB was done. Therefore. the "low yield" quoted for ENB must be taken in context of the most challenging cases and is in fact quite remarkable. Also, we have member participation in the NAVIGATE study (2), been published in March of 2019. This was a prospective, multicenter, global, single-arm, pragmatic cohort study of selected patients. The main outcome was safety, but with secondary analysis of yield. It was based on the more recent versions of the systems: prior meta-analysis and pooled data were based on obsolete versions. The NAVIGATE trial was associated with diagnostic yield of 72.9%. Sensitivity and negative predictive value for malignancy were 68.8% (range: 59.9%-68.8%) and 56.3% (range: 46.7%-63.8%), respectively. The lesions averaged 20 mm in diameter; 49% of lesions were less than 20mm. A properly selected procedure for the diagnosis of lung cancer requires consideration of both diagnosis and staging in the fewest possible procedures. Combining bronchoscopic techniques moves to the needed diagnostic steps and minimizes risks, without requiring additional procedures. Too often, patients undergo a CT guided biopsy. with the associated risks, and then need to have a mediastinal staging procedure. Allowing the use of the proper bronchoscopic techniques, which may include ENB, saves steps, complications and costs in these challenging patients (3.4). Finally, CT guided biopsy simply has a much higher risk for pneumothorax which adds need for secondary procedures (chest tube) and admission and is simply not practical in patients with central lesions, significant emphysema, or concerning lymph nodes (4). References included in response to Question 6
	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with enlarged mediastinal lymph node(s)	Enlarged Mediastinal Nodes This was an early indication for ENB which has been largely replaced by EBUS. One could consider it in the uncommon scenario in which linear EBUS is not available and the patient is having a procedure for a peripheral nodule in any case.
	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with lung tumor(s) who need fiducial marker placement prior to treatment.	Fiducial Marker Placement Fiducial markers are needed in some situations for targeted radiation therapy and localization for VATS resection. The lung moves during breathing, and proper targeting of tumors while accounting for respiratory variation minimizes damage to uninvolved tissue, particularly with stereotactic radiation therapy. A fiducial marker can be placed with bronchoscopic guidance or percutaneously. ENB has been shown to be an accurate and safe way to deploy fiducial markers of several different kinds (5). When needed, placement can be done as a standalone procedure or at the same time

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#	Indications	Rationale
		as a diagnostic procedure (6). The key advantage to ENB placement is the markedly reduced risk of pneumothorax compared to the transthoracic approach. Realize that the patients being treated with targeted radiation are typically those with advanced respiratory disease who cannot undergo surgical resection. They are also more at risk for pneumothorax and resultant further complications. As the markers need to be near and not necessarily in a lesion, the accuracy advantage of a transthoracic approach is far outweighed by the safety advantage of ENB over a transthoracic approach. References included in response to Question 6.

NR = not reported

- Describe any relevant expertise that may be necessary to perform this procedure.

#	Response
1	Bronchoscopists performing ENB require specific training in the procedure. The evidence summary refers to the procedure "administered in the outpatient setting by cancer specialists." While it is done by experienced bronchoscopists who may also have expertise in cancer, they are not oncologists.

- Based on the evidence and your clinical experience for each of the clinical indications described below:
  - Respond YES or NO for each clinical indication whether the intervention would be expected to provide a clinically meaningful improvement in net health outcome; AND
  - Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	Indications	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with suspicious peripheral pulmonary lesion(s)	Yes					X
2	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with enlarged mediastinal lymph node(s)	No					X
3	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with lung tumor(s) who need fiducial marker placement prior to treatment.	Yes					X

NR = not reported

- Based on the evidence and your clinical experience for each of the clinical indications described below:
  - Respond YES or NO for each clinical indication whether this intervention is consistent with generally accepted medical practice; AND
  - Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	Indications	Yes/ No	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for	Yes					X

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#	Indications	Yes/ No	Low Confidence	Intermediate Confidence	High Confidence
	individuals with suspicious peripheral pulmonary lesion(s)				
2	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with enlarged mediastinal lymph node(s)	No			X
3	Use of electromagnetic navigation bronchoscopy with flexible bronchoscopy for individuals with lung tumor(s) who need fiducial marker placement prior to treatment.	Yes			X

NR = not reported

- Additional narrative rationale or comments regarding the clinical context or specific clinical pathways for this topic and/or any relevant scientific citations (including the PMID) with evidence that demonstrates health outcomes you would like to highlight.

#	Additional Comments
1	In summary, ENB, when used as an option in the armamentarium of the bronchoscopist, is a highly useful and low-risk modality for proper diagnosis and staging of lung cancer patients. Data cited in comments above. References included in response to Question 6.

NR = not reported

- Is there any evidence missing from the attached draft review of evidence that demonstrates clinically meaningful improvement in net health outcome?

#	YES / NO	Citations of Missing Evidence
1	Yes	1. Ost DE, Ernst A, Lei X, et al. Diagnostic Yield and Complications of Bronchoscopy for Peripheral Lung Lesions. Results of the AQuIRE Registry. Am J Respir Crit Care Med. 2016;193(1):68-77. PMID: 26367186 2. Folch EE, Pritchett MA, Nead MA, et al. Electromagnetic Navigation Bronchoscopy for Peripheral Pulmonary Lesions: One-Year Results of the Prospective, Multicenter NAVIGATE Study. J Thorac Oncol. 2019;14(3):445-458. PMID: 30476574 3. Almeida FA, Casal RF, Jimenez CA, et al. Quality gaps and comparative effectiveness in lung cancer staging: the impact of test sequencing on outcomes. Chest. 2013;144(6):1776-1782. PMID: 23703671 4. Munoz ML, Lechtzin N, Li QK, et al. Bronchoscopy with endobronchial ultrasound-guided transbronchial needle aspiration vs transthoracic needle aspiration in lung cancer diagnosis and staging. J Thorac Dis. 2017;9(7):2178-2185. PMID: 28840019 5. Nabavizadeh N, Zhang J, Elliott DA, et al. Electromagnetic Navigational Bronchoscopy-guided Fiducial Markers for Lung Stereotactic Body Radiation Therapy. J Bronchology Interv Pulmonol. 2014;21(2): 123-130. PMID: 24739685 6. Bowling MR, Folch EE, Khandhar SJ, et al. Fiducial marker placement with electromagnetic navigation bronchoscopy: a subgroup analysis of the prospective, multicenter NAVIGATE study. Ther Adv Respir Dis. 2019;13:1753466619841234. PMID: 30958102

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

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

- Results/reports of tests performed
- Procedure report(s)

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Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple
	31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])
HCPCS	A4648	Tissue marker, implantable, any type, each
	C7509	Bronchoscopy, rigid or flexible, diagnostic with cell washing(s) when performed, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
	C7510	Bronchoscopy, rigid or flexible, with bronchial alveolar lavage(s), with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
	C7511	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with computer-assisted image-guided navigation, 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 3D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., 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
12/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

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For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status
In making a determination that any procedure, treatment, therapy, drug, biological product, facility, equipment, device, or supply is "experimental or investigational" by the Plan, the Plan shall refer to evidence from the national medical community, which may include one or more of the following sources:

1. Evidence from national medical organizations, such as the National Centers of Health Service Research.
2. Peer-reviewed medical and scientific literature.
3. Publications from organizations, such as the American Medical Association (AMA).
4. Professionals, specialists, and experts.
5. Written protocols and consent forms used by the proposed treating facility or other facility administering substantially the same drug, device, or medical treatment.
6. An expert physician panel selected by one of two organizations, the Managed Care Ombudsman Program of the Medical Care Management Corporation or the Department of Managed Health Care.

Feedback

Blue Shield of California Promise Health Plan is 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 Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

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

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.

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