Medical Policy Manual Surgery, Policy No. 179

Electromagnetic Navigation Bronchoscopy

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a three-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy.

MEDICAL POLICY CRITERIA

I. Electromagnetic navigation bronchoscopy may be considered **medically necessary** when either of the following criteria (A. or B.) are met:

   A. For the evaluation of suspicious peripheral pulmonary lesion(s); or

   B. For fiducial marker placement prior to treatment of lung tumors when flexible bronchoscopy alone or with endobronchial ultrasound are considered inadequate to accomplish the procedure.

II. Electromagnetic navigation bronchoscopy is considered **investigational** when the policy criteria above are not met, and for all other indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Confocal Laser Endomicroscopy, Medicine, Policy No. 151
2. Whole Body CT Screening, Radiology, Policy No. 40

BACKGROUND

The purpose of ENB is to allow navigation to distal regions of the lungs so that suspicious lesions can be biopsied and to allow for placement of fiducial markers.

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography (CT) scans. (Note that whole-body CT tests for screening are considered investigational; see related policy Radiology No. 40). Although most of these nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when cancer is diagnosed later in the disease course. The method used to diagnosis lung cancer depends on a number of factors, including lesion size and location, as well as the clinical history and status of the patient. There is generally greater diagnostic success with centrally located and larger lesions.

Peripheral lung lesions and solitary pulmonary nodules (SPN; most often defined as asymptomatic nodules less than 6 mm) are more difficult to evaluate than larger, centrally located lesions. There are several options for diagnosing them; none of the methods are ideal for safely and accurately diagnosing malignant disease. Lung biopsy is the gold standard for diagnosing pulmonary nodules but is an invasive procedure. Sputum cytology is the least invasive approach. Reported sensitivity rates for sputum cytology are relatively low and vary widely across studies. Additionally, 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 is a minimally invasive procedure and is an established approach to evaluating 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, less than 1.5 cm in diameter, the sensitivity may be as low as 10%.[1 2]

Recent advances in technology have led to enhancements that may increase the yield of established diagnostic methods. CT 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 (EBUS) by radial probes, previously used in the perioperative staging of lung cancer, can also be used to locate and guide sampling of peripheral lesions. EBUS is reported to increase the diagnostic yield of flexible bronchoscopy to at least 82%, regardless of the size and location of the lesion.[1] Transthoracic needle aspiration (TTNA) 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%–24% of patients, and 5%–14% require insertion of a chest tube. Positron emission tomography (PET) scans are also highly sensitive for evaluating pulmonary nodules, yet may miss small lesions less than 1 cm in size.

ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY

Another proposed enhancement to standard bronchoscopy is ENB using the InReach™ system. This technology uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. The three phases of the procedure

using the InReach™ system are as follows:

1. **Planning phase**: The previously taken CT scans are loaded onto a laptop computer, and proprietary software is used to construct a three-dimensional image of the patient's lungs, with anatomical landmarks identified. The file containing this information is transferred to a computer on the InReach™ computer console for use during the procedure;
2. **Registration phase**: A steerable navigation catheter is placed through the working channel of a standard bronchoscope. The anatomical landmarks identified in the planning phase are viewed on the three-dimensional image from phase 1, and these virtual images are correlated with the actual image from the video bronchoscope. The steerable navigation catheter is placed at the same site as the virtual markers, and the position of each is marked using a foot petal;
3. **Navigation phase**: The steerable navigation catheter is moved toward the target, and the real-time location of the catheter's tip is displayed on the CT images. When the navigation catheter reaches the target, it is locked in place and the working guide is retracted.

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 a transbronchial forceps to biopsy the lesion. In addition, the guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guide wire inserted through the catheter.

REGULATORY STATUS

In September 2004, the superDimension/Bronchus™ InReach™ system was cleared for marketing by the United States 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 determined that this device was substantially equivalent to existing bronchoscopic devices. It is indicated 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. In May 2012, superDimension was acquired by Covidien. The current version of the product is called i-Logic™ Electromagnetic Navigation Bronchoscopy.

In December 2009, the ig4™ EndoBronchial system was cleared for marketing by FDA through the 510(k) process. The system was considered to be substantially equivalent to the InReach™ and is marketed as the SPiN™ Drive system.

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

- December 2008: The LungPoint® virtual bronchoscopic navigation (VPN) system.
- June 2010: The bf-NAVI virtual bronchoscopic navigation (VPN) system.

EVIDENCE SUMMARY

Evaluation of electromagnetic navigation bronchoscopy (ENB) system as a diagnostic tool involves examining the following:

1. Navigation accuracy and biopsy success rate: The frequency with which the steerable

navigation catheter is able to reach a peripheral nodule previously identified on computed tomography (CT) scans, and, once reached, the frequency with which biopsies are successfully obtained.
2. Diagnostic accuracy compared to other methods. The ideal study design would include a gold standard (e.g., surgical biopsy and/or long-term follow-up) on all samples. Of particular interest is the negative predictive value (NPV), the proportion of patients with negative test results who are correctly diagnosed. If the NPV is high, we can have confidence that patients who test negative do not need additional interventions.
3. Complication rates compared to other methods of diagnosis.

A number of studies were identified that reported on navigation accuracy and biopsy success, diagnostic accuracy, and/or complication rates in the same article. None of the studies compared ENB to standard bronchoscopy, although many included patients who had failed or were considered likely failures with standard bronchoscopy. In addition, there are no comparative studies with transthoracic approaches. The comparative studies and the largest, most well-designed case series are described below.

ELECTRONIC NAVIGATION BRONCHOSCOPY FOR THE DIAGNOSIS OF PULMONARY LESIONS

Systematic Reviews

Folch (2020) published a systematic review of the sensitivity and safety of ENB for diagnosing peripheral pulmonary lesions suspected of cancer.[3] 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 studies. ENB had a pooled sensitivity of 77% (95% CI, 72% to 82%) and specificity of 100% (95% CI, 99% to 100%) for malignancy. ENB achieved a sufficient sample for ancillary tests in 90.9% (95% CI, 84.8%-96.9%) of cases. The risk of pneumothorax was 2.0% (95% CI, 1.0-3.0%). Because most studies did not use a proper reference standard, the authors reported that most studies had a high or unclear risk of bias regarding patient selection, index test, and the reference standard. This meta-analysis is also limited by small sample size of included studies, lack of control group in some studies, and high heterogeneity across studies.

Zhang (2015) published a systematic review which [4] updated a 2014 systematic review by Gex,[5] with the addition of newer studies. The Zhang review included prospective and retrospective studies of patients with peripheral nodules confirmed by radiographic evaluation that had more than 10 patients and reported the diagnostic yield of ENB for peripheral lung nodules or lesions. A total of 17 studies with 1,161 lung nodules or lesions in 1,106 patients met the eligibility criteria. The authors 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, the authors reported it was uncertain whether the selected patients were representative of the population that would undergo ENB in an actual clinical setting.

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.

Table 1. Meta-Analysis of Electromagnetic Navigation Bronchoscopy Performance Reported by Zhang (2015)

Variable	Rate (95% Confidence Interval), %
Sensitivity for malignancy	82 (79 to 85)
Specificity for malignancy	100 (98 to 100)
Positive likelihood ratio	18.67 (9.04 to 38.55)
Negative likelihood ratio	0.22 (0.15 to 0.32)
Diagnostic odds ratio	97.36 (43.75 to 216.69)
Sensitivity for malignancy	82 (79 to 85)

The Gex systematic review, which included 15 studies (total n=971 patients) reported somewhat different outcomes (see Table 2).

Table 2. Meta-Analysis of ENB Performance Reported by Gex (2014)

Variable	Rate (95% Confidence Interval), %
Navigation success	97.4 (95.4 to 98.5)
Diagnostic Yield	64.9 (59.2 to 70.3)
Sensitivity for Malignancy	71.1 (64.6 to 76.8)
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)

As reported by Gex, whereas the navigation success rate using ENB was generally very high, the diagnostic yield and NPV were relatively low. Moreover, in Zhang, the positive likelihood ratio was large but the negative likelihood ratio (0.22) suggested only a small decrease in the likelihood of disease following the test. (Zhang did not conduct a pooled analysis of diagnostic yield.) As stated at the beginning of this section, we are particularly interested in evidence that the test can correctly identify patients who do not have malignancy (ie, high NPV or low negative likelihood ratio). Studies included in the meta-analyses were limited because surgical biopsy was not used as the criterion standard; it is unclear whether follow-up was long enough to confirm ENB diagnoses. The pneumothorax rate following ENB was 5.9% in Zhang and 3.1% in Gex (1.6% required chest tube placement for pneumothorax). Zhang stated that 2 of the pneumothoraxes were induced by transbronchial biopsy and the others were unrelated to the ENB procedure.

Wang (2011) published a meta-analysis that evaluated the diagnostic yield of guided bronchoscopy techniques for evaluating pulmonary nodules (including ENB and EBUS, among others[6]). To be included in the review, studies needed to evaluate diagnostic yield and include more than 5 patients; studies could be prospective or retrospective. A total of 11 studies on ENB met the inclusion criteria. The pooled diagnostic yield was 67.0% (95% confidence interval [CI]: 62.6% to 71.4%), similar to the pooled estimate in the 2014 Gex meta-analysis. The authors did not report adverse events associated with individual guidance techniques; the overall pooled pneumothorax rate was 1.6%.

Randomized Controlled Trials

Eberhardt (2007) published the only RCT using ENB to evaluate peripheral pulmonary lesions.[7] This was also the only published study identified that consistently used surgical biopsy as a gold standard confirmation of diagnosis. Patients were randomized to receive ENB only, endobronchial ultrasound (EBUS) only, or the combination of ENB and EBUS. Whereas ENB is designed to help navigate to the target but cannot visualize the lesion, EBUS is not

able to guide navigation, but enables direct visualization of the target lesion before biopsy. The study included 120 patients who had evidence of peripheral lung lesions or solitary pulmonary nodules and who were candidates for elective bronchoscopy or surgery. In all three arms, only forceps biopsy specimens were taken, and fluoroscopy was not used to guide the biopsies. The primary outcome was diagnostic yield, the ability to yield a definitive diagnosis consistent with clinical presentation. If transbronchial lung biopsy was not able to provide a diagnosis, patients were referred for surgical biopsy. The mean size of the lesions was 26 + 6 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 of 39) with ENB only, 69% (27 of 39) with EBUS only, and 88% (35 of 40) with combined ENB/EBUS; the yield was significantly higher in the combined group. The negative predictive value for malignant disease was 44% (10 of 23) with ENB only, 44% (7 of 16) with EBUS only, and 75% (9 of 12) with combined ENB/EBUS. Note that the number of cases was small and thus the NPV is an imprecise estimate. Moreover, the authors state in the discussion that the yield in the ENB-only group is somewhat lower than in other studies and attribute this to factors such as the use of forceps for biopsy (rather than forceps and endobronchial brushes) and/or an improved diagnosis using a gold standard. The pneumothorax rate was 6%, which did not differ significantly among the three groups.

Nonrandomized studies

Select nonrandomized studies not included in the abovementioned meta-analyses are described here. Studies with small sample sizes have not been included.

Khandhar (2017) published a preplanned one-month interim analysis of the NAVIGATE study.[8] NAVIGATE is a prospective multicenter (n=37) analysis of outcomes in patients who received ENB in U.S. and European 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. The one-month analysis of the first 1,000 patients focused on safety outcomes; the primary end point was pneumothorax. Most of the first 1,000 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 one-month follow-up, none was considered related to the ENB device, but one was deemed related to general anesthesia complications. Diagnostic outcomes will be reported at the 12- and 24-month analyses; the authors noted that the follow-up time was not long enough at one month to verify true positives and true negatives.

In 2016, Ost published data from the AQuiRE Registry, a study of consecutive patients from multiple centers who underwent transbronchial biopsy for evaluation of peripheral lung lesions.[9] 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 EBUS or ENB, 57.0% with EBUS alone, 38.5% with ENB alone, and 47.1% with ENB plus EBUS. 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.

Steinfort (2016) published findings on 236 patients with 245 peripheral pulmonary lesions who underwent bronchoscopic investigation. EBUS and virtual bronchoscopy (VB) were used initially, and ENB was performed when EBUS could not locate the lesion or when rapid onsite cytologic evaluation (ROSE) could not be successfully performed. A total of 188 (77%) of 245 lesions were localized with EBUS and VB. ENB was used in the remaining 57 cases and lesion localization was achieved in an additional 17 cases (29.8% of those undergoing ENB). The addition of ENB increased the localization rate from 77% to 85.3%.[10] ROSE was diagnostic for 138 (71%) of the 188 lesions that were reached with EBUS and VB. Thus, the diagnostic yield of EBUS plus VB was 134 (54.7%) of 245 lesions. An additional 9 (15.8%) of 57 ENB procedures were diagnostic, improving the overall diagnostic yield from 54.7% to 58.4%. However, the authors noted that in only four of the nine procedures was the diagnostic outcome clearly attributable to accurate localization of the image with ENB. The authors did not conduct statistical analyses of diagnostic yield with EBUS versus EBUS with ENB.

Two prospective observational studies have examined the sequential use of ENB; EBUS was used initially, with the addition of ENB when EBUS failed to reach or diagnose the lesion. Chee (2013) published a study that included 60 patients with peripheral pulmonary lesions.[11] Patients either had a previous negative CT-guided biopsy or did not have one due to technical difficulties. An attempt was first made to identify the lesion using peripheral EBUS and, if not identified, then an ENB system was used. Nodules were identified by EBUS 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 EBUS 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 EBUS alone was not statistically significant (p=0.125). The rate of pneumothorax was 8% (5/60 patients); the addition of ENB did not alter the pneumothorax rate.

Section Summary

The evidence for ENB for individuals with suspicious peripheral pulmonary nodules consists largely of nonrandomized studies, and a single published RCT comparing ENB to another novel diagnostic approach, EBUS, rather than to standard bronchoscopy or transthoracic needle aspiration. The most recent meta-analysis, which included 40 prospective and retrospective studies, reported a high navigation success rate but relatively low diagnostic yield and negative predictive value. Similar results were reported by earlier systematic reviews.All meta-analyses judged the quality of published studies to be low and at high risk of bias.

Significant limitations found in the literature on ENB utilization is described below:

- There was a lack of clear patient selection criteria.
- Diagnostic yield, the ability to determine a conclusive diagnosis, of ENB per lesion in the available studies ranged from 57% to 84%; a 2020 meta-analysis found a pooled diagnostic yield of 64.9%.
- There is insufficient data on the potential use of ENB in biopsy of mediastinal lymph nodes.
- Due to the small number of patients in individual studies, there is limited evidence on complications from the procedure and adverse effects such as pneumothorax. Studies have not compared clinically significant pneumothorax rates with ENB versus needle biopsy.

- Data are insufficient to identify potential patient selection criteria for ENB. Published studies on factors associated with ENB diagnostic success have identified factors e.g., larger lesions (over 2 cm) that increase success but have not consistently identified characteristics that might aid with patient selection.

ELECTRONIC NAVIGATION BRONCHOSCOPY FOR THE DIAGNOSIS OF MEDIASTINAL LYMPH NODES

Systematic Reviews

No systematic reviews of electronic navigation bronchoscopy for the diagnosis of mediastinal lymph nodes were identified.

Randomized Controlled Trials

Diken (2015) published an RCT of ENB for the diagnosis of mediastinal lymph nodes (MLN). The trial included 94 patients with mediastinal lymphadenopathy with a short axis greater than 1 cm on CT and/or increased uptake on positron emission tomography.[8] Patients were randomized to conventional transbronchial needle aspiration (TNBA; n=50) or ENB-guided TNBA (n=44). All samples were evaluated by a blinded cytopathologist. Sampling success was defined as presence of lymphoid tissue in the sample and diagnostic success was the ability to make a diagnosis using the sample. Diagnoses were confirmed by one 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 TNBA group ($p<0.001$); diagnostic success was 72.8% in the ENB group and 42.2% in the conventional TNBA group ($p<0.001$). When samples were stratified by MLN size, both sampling success and diagnostic success were significantly higher with ENB than conventional TNBA in MLNs 15 mm or less and more than 15 mm. The authors noted that, although EBUS-guided TBNA has been shown to have higher diagnostic yields than conventional TNBA, EBUS was not compared to ENB because it was not available at the institution in Turkey where the study was conducted. No pneumothorax or other major adverse effects were reported for either group.

Nonrandomized Studies

Nonrandomized studies of ENB for the diagnosis of MLN are limited by small samples sizes, and inconsistent protocols for confirming diagnosis, though most authors report patients were followed for a confirmed diagnosis.

Section Summary

There are fewer studies of ENB for diagnosing MLN than for diagnosis of pulmonary lesions. One RCT identified found higher sampling and diagnostic success with ENB-guided TNBA than with conventional TNBA. EBUS, which has been shown to be superior to conventional TNBA, was not used as the comparator. The RCT did not report diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies. Overall, the evidence is insufficient to determine the added benefit of ENB compared to standard techniques for diagnosing mediastinal lymph nodes.

ELECTRONIC NAVIGATION BRONCHOSCOPY FOR THE PLACEMENT OF FIDUCIAL MARKERS

Evaluation of ENB as an aid to 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.

Randomized Controlled Trials

No RCTs using ENB as an aid to placement of fiducial markers were identified.

Nonrandomized Studies

Only one study was identified that compared fiducial marker placement with ENB with another method of fiducial marker placement; it was not randomized. This study, by Kupelian (2007) included 28 patients scheduled for radiotherapy for early-stage lung cancer.[10] Follow-up data were available for 23 (82%) patients; 15 had markers placed transcutaneously under CT or fluoroscopic guidance, and eight patients had markers placed transbronchially with ENB. At least one 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 rate of pneumothorax; 8 of 15 patients with transcutaneous placement developed pneumothorax, six of which required chest tubes. In contrast, none of the eight patients with transbronchial placement developed pneumothorax. This study had a small sample size and a substantial dropout rate.

Several case series were identified.[12-19] Studies with the largest sample sizes are described next. In the interim analysis of the NAVIGATE study (described above), 1000 patients received ENB, 210 of whom received 417 fiducial markers.[18] 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. Timing of follow-up imaging was not specified. ENB-related adverse events included eight (4%) cases of pneumothorax (grade ≥2), three cases of respiratory failure (grade ≥4), and a single bronchopulmonary hemorrhage (grade 1).

Bolton (2015) retrospectively reported on ENB fiducial marker placement in 64 patients (68 lung lesions) for guiding stereotactic radiotherapy.[13] 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 end point, 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 three (5%) unplanned hospital admissions, two cases of respiratory failure, and two cases of pneumothorax.

Schroeder (2010) reported on findings from a single-center prospective study with 52 patients who underwent placement of fiducial markers using ENB with the InReach™ system.[16] Patients all had peripheral lung tumors; 47 patients had inoperable tumors and 5 patients refused surgery. Patients were scheduled to receive tumor ablation using the CyberKnife stereotactic radiosurgery, which involves 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; 17 linear fiducial markers in four patients and 217 coil spring fiducial markers in 49 patients. CyberKnife planning CT scans were performed between 7 and 14 days after fiducial marker placement. The planning CT scans showed that 215 of 217 coil spring markers (99%) and 8 of 17 linear

markers (47%) markers remained in place, indicating a high success rate for coil spring markers. Three patients developed pneumothorax; two were treated with chest tubes, and one received observation-only.

Section Summary

There is insufficient evidence to determine the safety and efficacy of ENB used for fiducial marker placement. There are only a few published studies with small numbers of patients and only one study compared ENB to another method of fiducial marker placement.

PRACTICE GUIDELINE SUMMARY

NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN)

The NCCN clinical practice guideline on non-small cell lung cancer (v3.2025) states 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.[20] ENB is not addressed in the guidelines for small cell lung cancer.

- Patients with central masses and suspected endobronchial involvement should undergo bronchoscopy.
- Patients with pulmonary nodules may benefit from navigational bronchoscopy, radial EBUS or TTNA.
- Patients with suspected nodal disease should by biopsied by EBUS, endoscopic ultrasound (EUS), navigational bronchoscopy, or mediastinoscopy.

AMERICAN COLLEGE OF CHEST PHYSICIANS (ACCP)

In 2013, ACCP issued updated guidelines on the diagnosis of lung cancer.[21] Regarding ENB, the guideline 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 authors 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 rated as Grade 1C, defined as “Strong recommendation, low- or very-low-quality evidence.”

SUMMARY

There is enough research to show that electromagnetic navigation bronchoscopy (ENB) improves health outcomes compared to standard approaches to diagnose lung tumors for people with suspicious pulmonary lesions and for placement of fiducial markers prior to lung tumor treatment. While available studies are limited by small sample size, the evidence suggests that ENB provides high navigational success and reduces the risk for pneumothorax and other complications of transthoracic needle biopsy. Therefore, in patients with suspicious pulmonary lesions or patients who require placement of fiducial markers prior to lung tumor treatment, ENB may be considered medically necessary when the policy criteria are met.

There is not enough research to show that electromagnetic navigation bronchoscopy (ENB) improves health outcomes for indications other than diagnosis of peripheral pulmonary

lesions or fiducial marker placement prior to lung tumor treatment. Therefore, ENB is considered investigational when policy criteria are not met and for all other indications, including but not limited to use as a diagnostic technique for patients with enlarged mediastinal lymph nodes.

REFERENCES

1. Rivera MP,Mehta AC. Initial diagnosis of lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition). *Chest.* 2007;132(3 Suppl):131S-48S. PMID: 17873165
2. Tape TG. *Solitary pulmonary nodule. In Black ER, Bordley DR, Tape TG et al., eds. Diagnostic Strategies for Common Medical Problems*. 2nd ed. Philadelphia, PA: American College of Physicians, 1999, pp.
3. Folch EE, Labarca G, Ospina-Delgado D, et al. Sensitivity and Safety of Electromagnetic Navigation Bronchoscopy for Lung Cancer Diagnosis: Systematic Review and Meta-analysis. *Chest.* 2020;158(4):1753-69. PMID: 32450240
4. Zhang W, Chen S, Dong X, et al. Meta-analysis of the diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules. *Journal of thoracic disease.* 2015;7(5):799-809. PMID: 26101635
5. Gex G, Pralong JA, Combescure C, et al. Diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules: a systematic review and meta-analysis. *Respiration.* 2014;87:165-76. PMID: 24401166
6. Wang Memoli JS, Nietert PJ,Silvestri GA. Meta-analysis of guided bronchoscopy for the evaluation of the pulmonary nodule. *Chest.* 2012;142(2):385-93. PMID: 21980059
7. Eberhardt R, Anantham D, Ernst A, et al. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized controlled trial. *Am J Respir Crit Care Med.* 2007;176(1):36-41. PMID: 17379850
8. Diken OE, Karnak D, Ciledag A, et al. Electromagnetic navigation-guided TBNA vs conventional TBNA in the diagnosis of mediastinal lymphadenopathy. *The clinical respiratory journal.* 2015;9(2):214-20. PMID: 25849298
9. 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
10. Steinfort DP, Bonney A, See K, et al. Sequential multimodality bronchoscopic investigation of peripheral pulmonary lesions. *The European respiratory journal.* 2016;47(2):607-14. PMID: 26541529
11. Chee A, Stather DR, Maceachern P, et al. Diagnostic utility of peripheral endobronchial ultrasound with electromagnetic navigation bronchoscopy in peripheral lung nodules. *Respirology.* 2013;18(5):784-9. PMID: 23521707
12. Minnich DJ, Bryant AS, Wei B, et al. Retention Rate of Electromagnetic Navigation Bronchoscopic Placed Fiducial Markers for Lung Radiosurgery. *The Annals of thoracic surgery.* 2015;100(4):1163-5; discussion 65-6. PMID: 26228602
13. Bolton WD, Richey J, Ben-Or S, et al. Electromagnetic Navigational Bronchoscopy: A Safe and Effective Method for Fiducial Marker Placement in Lung Cancer Patients. *The American surgeon.* 2015;81(7):659-62. PMID: 26140883
14. Nabavizadeh N, Zhang J, Elliott DA, et al. Electromagnetic navigational bronchoscopy-guided fiducial markers for lung stereotactic body radiation therapy: analysis of safety, feasibility, and interfraction stability. *Journal of bronchology & interventional pulmonology.* 2014;21(2):123-30. PMID: 24739685

15. Anantham D, Feller-Kopman D, Shanmugham LN, et al. Electromagnetic navigation bronchoscopy-guided fiducial placement for robotic stereotactic radiosurgery of lung tumors: a feasibility study. *Chest.* 2007;132(3):930-5. PMID: 17646225
16. Schroeder C, Hejal R,Linden PA. Coil spring fiducial markers placed safely using navigation bronchoscopy in inoperable patients allows accurate delivery of CyberKnife stereotactic radiosurgery. *J Thorac Cardiovasc Surg.* 2010;140(5):1137-42. PMID: 20850809
17. Hagmeyer L, Priegnitz C, Kocher M, et al. Fiducial marker placement via conventional or electromagnetic navigation bronchoscopy (ENB): an interdisciplinary approach to the curative management of lung cancer. *The clinical respiratory journal.* 2016;10(3):291-7. PMID: 25308297
18. Khandhar SJ, Bowling MR, Flandes J, et al. Electromagnetic navigation bronchoscopy to access lung lesions in 1,000 subjects: first results of the prospective, multicenter NAVIGATE study. *BMC pulmonary medicine.* 2017;17(1):59. PMID: 28399830
19. Rong Y, Bazan JG, Sekhon A, et al. Minimal Inter-Fractional Fiducial Migration during Image-Guided Lung Stereotactic Body Radiotherapy Using SuperLock Nitinol Coil Fiducial Markers. *PloS one.* 2015;10(7):e0131945. PMID: 26158847
20. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology™. Non-Small Cell Lung Cancer. v3.2025. Secondary National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology™. Non-Small Cell Lung Cancer. v3.2025 [cited 2/12/2025]. 'Available from:' http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.
21. Rivera MP, Mehta AC,Wahidi MM. Establishing the diagnosis of lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest.* 2013;143:e142S-65S. PMID: 23649436

CODES

Codes	Number	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)
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
	C8005	Bronchoscopy, rigid or flexible, non-thermal transbronchial ablation of lesion(s) by pulsed electric field (pef) energy, including fluoroscopic and/or ultrasound 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.,

Codes	Number	Description
		aspiration[s]/biopsy[ies]) of lung(s) and all mediastinal and/or hilar lymph node stations or structures, and therapeutic intervention(s)
	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)

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