



Louisiana

Electromagnetic Navigation Bronchoscopy

Policy # 00247

Original Effective Date: 01/20/2010

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Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers electromagnetic navigation bronchoscopy (ENB) for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes to be **investigational**.*

Based on review of available data, the Company considers electromagnetic navigation bronchoscopy (ENB) for the placement of fiducial markers to be **investigational**.*

Background/Overview

PULMONARY NODULES

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography (CT) 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

The method used to diagnose lung cancer depends on a number of factors, including lesion size, shape and 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 them; none of the methods is ideal for safely and accurately diagnosing malignant disease. 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. Lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure.

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Recent advances in technology 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 lesion size or location.

Another proposed enhancement to standard bronchoscopy is ENB. 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. 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. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration

In September 2004, the SuperDimension/Bronchus™ inReach™ system (superDimension, Herzliya, Israel) was cleared for marketing by the U.S. 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, Minneapolis, MN).

In December 2009, the ig4™ EndoBronchial system (Veran Medical, St. Louis, MO) was cleared for marketing by 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™.

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

- In December 2008, the LungPoint® virtual bronchoscopic navigation (VPN) system (Broncus Technologies, Mountain View, CA).
- In June 2010, the bf-NAVI VPN system (Emergo Group, Austin, TX).

FDA product codes: JAK, LLZ.

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination.

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Rationale/Source

ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY TO AID IN DIAGNOSIS OF PULMONARY LESIONS

Evaluation of ENB as a navigation tool to permit diagnosis of pulmonary lesions involves examining the:

1. Navigation accuracy and biopsy success rate: Navigation accuracy is the frequency with which the steerable navigation catheter is able to reach a peripheral nodule previously identified on CT scans, and, once reached, the frequency with which biopsies are successfully obtained.
2. Diagnostic accuracy compared with other methods: The ideal study design would include a criterion standard (eg, 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 be confident that patients who test negative do not need additional interventions.
3. Complication rates compared with other methods of diagnosis.

Systematic Reviews

A systematic review of the literature on the diagnostic yield and safety of ENB was published in 2015 by Zhang et al. Reviewers updated a 2014 systematic review by Gex et al with 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. 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.

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 ENB Performance Reported by Zhang et al

Outcomes	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)

ENB: electromagnetic navigation bronchoscopy.

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

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Table 2. Meta-Analysis of ENB Performance Reported by Gex et al

Outcomes	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)

ENB: electromagnetic navigation bronchoscopy.

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.

Randomized Controlled Trials

Eberhardt et al (2007) published the only randomized controlled trial (RCT) to evaluate ENB for the diagnosis of pulmonary nodules. This trial used surgical biopsy as a criterion standard confirmation of diagnosis. Patients were randomized to ENB only, 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 unable to guide navigation but enables direct visualization of the target lesion before 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 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 surgical biopsy. The mean size of the lesions was 26 mm (SD=6).

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 EBUS only, and 88% (35/40) with ENB plus EBUS; the yield was significantly higher in the combined group. The NPV for malignant disease was 44% (10/23) with ENB only, 44% (7/16) with EBUS only, and 75% (9/12) with combined ENB and EBUS. Note that the number of cases was small, and thus the NPV is an imprecise

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

Uncontrolled Studies

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

In 2017, Khandhar et al published a preplanned 1-month interim analysis of the NAVIGATE study. 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 1-month analysis of the first 1000 patients focused on safety outcomes; the primary end point 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 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 1 month to verify true positives and true negatives.

The American College of Chest Physicians (ACCP) 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 (ACCP Quality Improvement Registry, Evaluation and Education), were published in 2016 by Ost et al. 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.

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. A 2013 study by Chee et al included 60 patients with peripheral pulmonary lesions. 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

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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.

In 2016, Steinfert et al published findings on 236 patients with 245 peripheral pulmonary lesions who underwent bronchoscopic investigation. EBUS and virtual bronchoscopy were used initially, and ENB was performed when EBUS could not locate the lesion or when rapid onsite cytologic evaluation could not be successfully performed. A total of 188 (77%) of 245 lesions were localized with EBUS and virtual bronchoscopy. 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%.

Rapid onsite cytologic evaluation was diagnostic for 138 (71%) of the 188 lesions reached with EBUS and virtual bronchoscopy. Thus, the diagnostic yield of EBUS plus virtual bronchoscopy 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 4 of the 9 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.

Section Summary: Electromagnetic Navigation Bronchoscopy to Aid in Diagnosis of Pulmonary Lesions

The evidence on ENB for diagnosis of pulmonary lesions includes meta-analyses, 1 RCT, and a number of observational studies. The most recent meta-analysis, which included 17 studies, reported a large pooled positive likelihood ratio but a modest negative likelihood ratio. Similarly, a 2014 meta-analysis with 15 studies found that navigation success was high, but diagnostic yield and NPV were relatively low. A high NPV or a small negative likelihood ratio is desirable because it indicates that patients who test negative would not need additional interventions. Both meta-analyses judged the quality of published studies to be low. The single RCT found higher diagnostic yield when both ENB and EBUS were used compared with either intervention alone, but did not include a group without either ENB or EBUS.

Most of the observational studies had small sample sizes. There are 2 large prospective multicenter uncontrolled studies. 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 EBUS. An interim analysis of the NAVIGATE study focused on safety outcomes in the first 1000 patients at 1 month. The rate of pneumothorax of any grade was 4.9% and the rate of grade 2 or higher was 3.2%.

The data are also insufficient to identify potential patient selection criteria. The meta-analyses identified lack of clear selection criteria as a key potential bias in the published literature. Overall, the evidence is insufficient to determine the added benefit of ENB compared with standard techniques for diagnosing of pulmonary lesions.

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ENB TO AID IN THE DIAGNOSIS OF MEDIASTINAL LYMPH NODE(S)

Randomized Controlled Trials

One RCT was identified on ENB for the diagnosis of mediastinal lymph nodes (MLN). The trial, published in 2015 by Diken et al, included 94 patients with mediastinal lymphadenopathy with a short axis greater than 1 cm on CT and/or increased uptake on positron emission tomography. Patients were randomized to conventional transbronchial needle aspiration (TNBA; n=50) or to ENB-guided TNBA (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 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 with 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.

Uncontrolled Studies

No large uncontrolled studies were identified that focused on ENB for the diagnosing of MLN. A 2007 series by Wilson et al included both patients with suspicious lung lesions and enlarged MLN. There was no consistent protocol for confirming 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 MLN were successfully reached, and tissue samples for biopsy were obtained from all of these. The primary study outcome was diagnostic yield on the day of the procedure; this was obtained for 64 (96%) of 67 of the lymph nodes reached.

Section Summary: ENB to Aid in the Diagnosis of Mediastinal Lymph Node(s)

There is less published literature on 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.

ENB TO AID IN PLACEMENT OF FIDUCIAL MARKERS PRIOR TO TREATMENT

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

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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.

Only 1 study was identified that compared fiducial marker placement with ENB with another method of fiducial marker placement; it was not randomized. This 2007 study, by Kupelian et al, included 28 patients scheduled for radiotherapy for early-stage lung cancer. 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 rate of pneumothorax; 8 of 15 patients with transcutaneous placement developed 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.

Several case series were identified. 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. 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 8 (4%) cases of pneumothorax (grade ≥ 2), 3 cases of respiratory failure (grade ≥ 4), and a single bronchopulmonary hemorrhage (grade 1).

In 2015, Bolton et al retrospectively reported on ENB fiducial marker placement in 64 patients (68 lung lesions) for guiding stereotactic radiotherapy. 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 3 (5%) unplanned hospital admissions, 2 cases of respiratory failure, and 2 cases of pneumothorax.

In 2010, Schroeder et al reported findings from a prospective study with 52 patients who underwent placement of fiducial markers using ENB. 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 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.

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Section Summary: ENB 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 case series. In the largest series, an interim analysis of the NAVIGATE study, the subjective assessment of outcome was that 9% were accurately replaced and 94% were retained at follow-up. Comparative data are needed to draw conclusions about the safety and efficacy of ENB for fiducial marker placement.

SUMMARY OF EVIDENCE

For individuals who have suspicious peripheral pulmonary lesion(s) who receive ENB with flexible bronchoscopy, the evidence includes meta-analyses, 1 RCT, and a number of observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. For ENB, a high NPV or small negative likelihood ratio is desirable because it indicates that patients who test negative would not need additional interventions. The most recent meta-analysis reported a large pooled positive likelihood ratio but a modest negative likelihood ratio. Similarly, a 2014 meta-analysis found that navigation success was high, but diagnostic yield and NPV were relatively low. Both meta-analyses judged the quality of published studies to be low. The single RCT found higher a diagnostic yield when both ENB and EBUS were used compared with either intervention alone, but did not include a group without ENB or EBUS. Most uncontrolled studies had small sample sizes. In the AQuiRE registry study, which included more than 500 patients receiving ENB in practice, diagnostic accuracy was lower than in other studies. A large multicenter uncontrolled study is underway. Known as NAVIGATE, an interim analysis of the first 1000 patients reported a 4.9% rate of pneumothorax of any grade and 3.2% rate for pneumothorax of grade 2 or higher. Findings for diagnostic accuracy from NAVIGATE are not yet available. Current data are insufficient to identify potential patient selection criteria or to determine the diagnostic accuracy of ENB when used in clinical practice. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, the evidence includes 1 RCT and observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. The RCT found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration (TNBA) than with conventional TNBA. EBUS, which has been shown superior to conventional TNBA, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, the evidence includes 1 controlled study and several uncontrolled studies. Relevant outcomes are other test performance measures, health status measures, and treatment-related morbidity. The controlled study compared markers placed transcutaneously under computed tomography or fluoroscopic guidance or transbronchially with ENB. However, data were only available for 8 patients who had markers placed with ENB. We identified several case series but need comparative data to draw conclusions about the safety and efficacy of ENB for fiducial marker placement. In the largest series, an

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interim analysis of the NAVIGATE study, the subjective assessment of outcome was that 9% were accurately replaced and 94% were retained at follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Louisiana

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01/07/2010	Medical Policy Committee approval
01/20/2010	Medical Policy Implementation Committee approval. New policy.
10/01/2010	Coding revision only
01/06/2011	Medical Policy Committee review
01/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014	Medical Policy Committee review
02/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/05/2018	Medical Policy Committee review
04/18/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2019

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Code Type	Code
CPT	31626, 31627
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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