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Medical Policy Manual

Topic: 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. 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.

- Biopsy

Lung biopsy is the gold standard for diagnosing pulmonary nodules, but is an invasive procedure.[1,2]

- Sputum cytology

  This 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

  Flexible bronchoscopy, a minimally invasive procedure, 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%.

  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

  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%–24% of patients, and 5%–14% require insertion of a chest tube.

- Positron emission tomography (PET)

  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 FDA through the 510(k) process. The system includes planning and navigation software, a disposable extended working channel, and a disposable steerable guide. 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.

MEDICAL POLICY CRITERIA

Electromagnetic navigation bronchoscopy is considered **investigational** for all indications, including but not limited to the following:

A. Use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes.

B. For the placement of fiducial markers.

SCIENTIFIC EVIDENCE

Diagnosis of Pulmonary Lesions and Mediastinal Lymph Nodes

Evaluation of electromagnetic navigation bronchoscopy **(**ENB**)** with the InReach™ 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.

Meta-Analysis

- A 2011 meta-analysis by Wang and colleagues evaluated the diagnostic yield of guided bronchoscopy techniques for evaluating pulmonary nodules (including ENB and EBUS, among others[3]). 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%). The pooled diagnostic yield of EBUS (20 studies) was 71.7% (95% CI: 66.5% to 75.7%). The authors did not report adverse events associated with individual guidance techniques; the overall pooled pneumothorax rate was 1.6%.

Randomized Controlled Trials (RCTs)

- Eberhardt and colleagues published the only randomized trial using ENB.[4] 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% (23/39) with ENB only, 69% (27/39) with EBUS only, and 88% (35/40) with combined ENB/EBUS; the yield was significantly higher in the combined group. The negative predictive value for malignant disease was 44% (10/23) with ENB only, 44% (7/16) with EBUS only, and 75% (9/12) 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

- In 2012, Brownback and colleagues retrospectively reported on 55 individuals older than 18 years who underwent ENB at their institution between 2008 and 2011[5]. Reasons for undergoing ENB included a solitary pulmonary nodule, pulmonary infiltrate or hilar lymphadenopathy that was not considered to be accessible by conventional bronchoscopy. ENB was considered successful if the ENB-directed biopsy resulted in a plausible histological diagnosis, or if additional procedures following a determination by ENB that the lesion was negative for malignancy confirmed the initial ENB diagnosis. Additional procedures for patients with negative or non-diagnostic ENBs included CT-guided transthoracic needle aspiration, surgical biopsy, or serial CT scans. Forty-one of the 55 ENB procedures performed led to a diagnosis and were considered successful (diagnostic yield: 74.5%). Twenty-five ENBs identified a carcinoma, 13 found no evidence of malignancy, and this was confirmed by other tests, and 3 revealed infection. Among the non-diagnostic studies, 11 were found to be malignant after additional procedures. Thus, the sensitivity of ENB for malignancy was 25 of 36 (sensitivity of 69.4%). The positive predictive value (PPV) for malignancy was 100% and the negative predictive value (NPV) for malignancy was 63.3%. When ENB failed to result in a diagnosis, the NPV was 54.2%. No post-procedure pneumothoraxes were identified in patients undergoing ENB. There were 2 cases of post-procedural hypoxemic respiratory failure; one patient required a chest tube.

- Several series sought to identify factors that increase the likelihood of successfully obtaining a diagnosis using ENB. For example, in 2012, Jenson and colleagues conducted a retrospective analysis of 92 consecutive ENB procedures conducted at 5 centers in the United States.[6] The overall diagnostic yield was 65% (60 of 92 procedures). Controlling for distance from the pleura, the diagnostic yield was significantly higher for lesions greater than 2 cm in size (76%) compared to those 2 cm or smaller (50%), p=0.01. After controlling for nodule size, the distance of the lesion from the pleura was not significantly associated with diagnostic yield. The lobar location of the nodule (i.e., right or left upper or lower lobe), the type of sampling method (i.e., needle aspiration, brushing, lavage and/or transbronchial biopsy) and the number of sampling methods were not significantly associated with diagnostic yield. The complication rate was 4%; there were 3 cases of pneumothorax and 1 episode of bleeding.

- A prospective 2012 study included 112 consecutive patients referred to a single center in Austria.[7] All patients were candidates for bronchoscopy of a solitary pulmonary lesion. In 94 of 112 patients (83.9%), ENB along with positron emission tomography-computed tomography (PET-CT) and rapid on-site cytopathologic evaluation (ROSE) led to the correct diagnosis, as confirmed by histology. A total of 17 (15%) lesions were benign, and 95 (85%) were malignant. As in the Jenson series, described above, the diagnostic yield was significantly higher for lesions greater than 2 cm in size (89.6%) than in those 2 cm or smaller (75.6%). Diagnostic yield was not significantly related to nodule location (upper lobe vs. lower lobe) or lung function (forced expiratory volume in 1 second (FEV1), % predicted). There were 2 cases of pneumothorax (1.8%); neither patient required a chest tube.

- In a study by Eberhardt and colleagues[8], 54 patients (55 lesions) underwent ENB for the evaluation of suspicious solitary pulmonary nodules. EBUS was used to confirm the location of the target lesion for research purposes, but was not used to guide navigation. The mean lesion size was 23 + 4 mm. All accessed lesions were sampled using both catheter aspiration (2 samples) and forceps biopsy (5 samples). All 55 lesions were reached with ENB and sampled. Patients were followed up until there was a definitive diagnosis or other procedures confirmed diagnosis. Diagnostic yield with ENB was the primary outcome. Two patients (2 lesions) were lost to follow-up and excluded from the analysis. In the remaining 53 patients, a definitive diagnosis was made using one or both types of sampling in 40 lesions (75.5%) after ENB; 34 of these lesions were malignant. The remaining 13 cases were considered ENB failures; all were subsequently found to have malignant lesions. ENB identified 34 of 47 positive cases (sensitivity=75%). The 6 patients who tested negative with ENB were later confirmed as true negatives. Thus, the specificity of ENB was 100%, although this was based on a small number of cases. Overall, sampling using the catheter aspiration had a significantly higher diagnostic yield than sampling using forceps (p=0.035). In 36 of 40 cases (90%), the diagnosis was made using catheter aspiration but in only 22 of 40 cases (45%), the diagnosis was made using forceps.

- A 2013 prospective study by Chee and colleagues investigated the use of ENB in cases where peripheral EBUS alone was unable to obtain a diagnosis.[9] The study included 60 patients with peripheral pulmonary lesions. Patients either had a previous negative CT-guided biopsy or did not have a CT-guided biopsy due to technical difficulties. An attempt was first made to identify the lesion using peripheral EBUS and, if the lesion was not identified, then an ENB system was used. Nodules were identified on ultrasound image by EBUS alone in 45 of 60 cases (75%). ENB was used in 15 cases (25%), and in 11 of these cases (73%), 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 of 60 cases (50%). The extent of improved diagnosis with ENB over EBUS alone was not statistically significant (p=0.125). The rate of pneumothorax was 8% (5 of 60 patients); the addition of ENB did not alter the pneumothorax rate.

Conclusions

The evidence consists largely of case series, and the single published RCT compared ENB to another novel diagnostic approach, EBUS, rather than to standard bronchoscopy or transthoracic needle aspiration. Significant limitations found in the literature on ENB utilization is described below:

- Diagnostic yield, the ability to determine a conclusive diagnosis, of ENB per lesion in the available studies ranged from 57% to 84%; a 2011 meta-analysis found a pooled diagnostic yield of 67%.
- 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.

Overall, the evidence is insufficient to determine the added benefit of ENB compared to standard

techniques for diagnosing pulmonary lesions and mediastinal lymph nodes.

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 compared with using another method or when no fiducial markers are used. This policy evaluates the use of ENB to place fiducial markers; it does not evaluate the role of fiducial markers in radiation therapy.

Randomized Controlled Trials (RCTs)

No RCTs were found.

Nonrandomized Studies

- Kupelian and colleagues included 28 patients scheduled for radiation therapy for early-stage lung cancer.[10] Follow-up data were available for 23 patients; 15 had markers placed transcutaneously under CT or fluoroscopic guidance and 8 patients had markers placed transbronchially using the superDimension system. 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 the course of 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 which required chest tubes. In contrast, none of the 8 patients with transbronchial placement developed pneumothorax.

- Ananthan and colleagues included 9 patients with peripheral lung tumors who were considered nonsurgical candidates and were scheduled to undergo treatment with robotic stereotactic radiosurgery (Cyberknife).[11] Using the SuperDimension system, 39 fiducial markers were successfully placed in 8 of the 9 patients. A total of 35 of the 39 markers (90%) were still in place at radiosurgery planning 7 to 10 days later. No complications were observed. Both of these studies involved small sample sizes and were essentially feasibility studies; neither reported on clinical outcomes after tumor treatment.

- In 2010, Schroeder and colleagues reported on findings from a single-center prospective study with 52 patients who underwent placement of fiducial markers using ENB with the InReach system.[12] 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 4 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 215/217 coil spring markers (99%) and 8/17 linear markers (47%) 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.

Conclusions

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.

Clinical Practice Guidelines

National Comprehensive Cancer Network (NCCN)

The 2014 NCCN clinical practice guideline on non-small cell lung cancer 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.[13]

- For patients with central masses and suspected endobronchial involvement, bronchoscopy is preferred.
- For patients with peripheral (outer one-third) nodules, either navigation bronchoscopy, radial EBUS or TTNA is preferred.
- For patients with suspected nodal disease, EBUS, navigation biopsy or mediastinoscopy is preferred.

American College of Chest Physicians (ACCP)

In 2013, ACCP issued updated guidelines on the diagnosis of lung cancer.[14] 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 as Grade 1C, defined as "Strong recommendation, low- or very-low-quality evidence."

Summary

Overall, data are insufficient to determine the risks and benefits of electromagnetic navigation bronchoscopy (ENB) compared to standard approaches to diagnose peripheral lesions; therefore, ENB is considered investigational for this indication. The data are also insufficient to identify which patients might benefit from ENB. Eligibility criteria of existing studies were variable, and in some cases, not well-defined; therefore, it is not clear whether this would be most appropriate as a first-line or second-line diagnostic approach.

In addition, insufficient data are available on the safety and efficacy of ENB used for fiducial marker placement. There are only a few small studies and only one compared ENB to another method of fiducial marker placement. Thus, use of this technology is considered investigational.

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CROSS REFERENCES

Whole Body CT Screening, Radiology, Policy No. 40

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy, Surgery, Policy No. 16

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	None	