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Electromagnetic Navigation Bronchoscopy

Policy # 00247

Original Effective Date: 01/20/2010

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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

Electromagnetic navigation bronchoscopy 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 screening for lung cancer and whole-body CT tests for screening are considered investigational). 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 diagnose 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. 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 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%. The diagnostic accuracy of transthoracic needle aspiration for SPNs 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



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sensitive for evaluating pulmonary nodules, yet may miss small lesions less than 1 cm in size. Lung biopsy is the gold standard for diagnosing pulmonary nodules but is an invasive procedure.

Recent advances in technology have led to enhancements that may increase the yield of established diagnostic methods. Computed tomography scanning equipment can be used to guide bronchoscopy and bronchoscopic transbronchial needle biopsy but have the disadvantage of exposing the patient and staff to radiation. Endobronchial ultrasound (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. Endobronchial ultrasound is reported to increase the diagnostic yield of flexible bronchoscopy to at least 82%, regardless of the size and location of the lesion.

Another proposed enhancement to standard bronchoscopy is ENB. This technology uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. The InReach™[‡] system was the first ENB system cleared for marketing by the U.S. Food and Drug Administration (FDA). The three phases of the procedure using the InReach system are as follows:

1. **Planning phase:** 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 pedal;
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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration

In September 2004, the superDimension/Bronchus™[‡] (superDimension Ltd, Herzliya, Israel) InReach system was cleared for marketing by the 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 (U.S.

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headquarters in Mansfield, MA). The current version of the product is called i-Logic™[‡] Electromagnetic Navigation Bronchoscopy.

In December 2009, the ig4™[‡] EndoBronchial system (Veran Medical; St. Louis, MO) was cleared for marketing by the FDA through the 510(k) process. The system was considered to be substantially equivalent to the InReach system and is marketed as the SPiN™[‡] Drive system.

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

- December 2008: The LungPoint®[‡] virtual bronchoscopic navigation (VPN) system (Broncus Technologies, Mountain View, CA).
- June 2010: The bf-NAVI VPN system (Emergo Group, Austin, TX)

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination.

Rationale/Source

All published studies on ENB described in this review have used the superDimension InReach system. The literature on use of ENB as a diagnostic aid and for placement of fiducial markers is described below.

Electromagnetic Navigation Bronchoscopy for the Diagnosis of Pulmonary Lesions and Mediastinal Lymph Nodes

Evaluation of EBN as a diagnostic tool involves examining the:

- 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 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.

Eberhardt and colleagues published the only randomized controlled trial (RCT) to date using ENB. This study consistently used surgical biopsy as a gold standard confirmation of diagnosis. Patients were randomized to receive 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 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 SPNs 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 was not able to provide a diagnosis, patients were referred for surgical biopsy. The mean size of the lesions was 26 + 6 mm.

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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 NPV 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 stated 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 3 groups.

In addition to the Eberhardt RCT, a number of prospective and retrospective case series using ENB have been published. A 2011 meta-analysis by Wang Memoli and colleagues evaluated the diagnostic yield of guided bronchoscopy techniques for evaluating pulmonary nodules (including ENB and EBUS, among others). 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%.

Selected representative series are described below:

In 2012, Brownback and colleagues retrospectively reported on 55 individuals older than 18 years who underwent ENB at their institution between 2008 and 2011. Reasons for undergoing ENB included a solitary pulmonary nodule, pulmonary infiltrate or hilar lymphadenopathy that was not considered to be accessible by conventional bronchoscopy. Electromagnetic navigation bronchoscopy 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 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.

In a large series published in 2007, Wilson and colleagues reviewed the records of 248 consecutive patients who were referred for evaluation of suspicious peripheral lung lesions, enlarged mediastinal lymph nodes, or both. There was no consistent protocol for confirming diagnosis, although the authors stated that most patients were followed up for confirmation of diagnosis. Electromagnetic navigation bronchoscopy was



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used to locate, register, and navigate to lung lesions. Once navigation was completed, fluoroscopic guidance was used to verify its accuracy and to aid in the biopsy or transbronchial needle aspiration. Forceps were used to sample lung lesions. The mean size of the targeted peripheral lung lesions was 21 + 14 mm. A total of 266 of 279 (95%) of the targeted peripheral lung lesions and 67 of 71 (94%) of the lymph nodes 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 151 of 279 (54%) of the peripheral lung lesions that were reached and 64 of 67 of the lymph nodes that were reached. Ninety of the lung lesions were malignant, and 61 were benign. Another 16 peripheral lung lesions were followed-up and later confirmed as true negatives. The final status of 89 lesions (approximately 30% of the targeted lesions) was inconclusive. There were 8 complications: 3 cases of moderate bleeding (none required transfusion), 3 cases of pneumothorax (none required treatment), 1 case of hematoma (did not require treatment), and 1 case of pneumonia/chronic obstructive pulmonary disease exacerbation (treated on outpatient basis).

In a 2007 prospective study, Eberhardt and colleagues reported on 89 patients who underwent ENB. All patients had evidence of peripheral lung lesions or SPNs without evidence of endobronchial pathology. The mean size of the targeted lesions was 24 + 8 mm. Electromagnetic navigation bronchoscopy yielded a definitive diagnosis in 52 lesions, and another 10 lesions that were followed up for a mean of 16 months appear to have been true-negatives. The authors reported a specificity of 100% and an NPV for malignant disease of 44%. Complications included 2 asymptomatic cases of pneumothorax that were identified; no treatment was necessary.

A 2013 prospective study by Chee and colleagues in Canada investigated the use of ENB in cases where peripheral EBUS alone was unable to obtain a diagnosis. 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%). Electromagnetic navigation bronchoscopy 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.

Several series sought to identify factors that increase the likelihood of successfully obtaining a diagnosis using ENB. Diagnostic yield with ENB was found to be higher for larger lesions, i.e. greater than 2cm in size, compared to smaller lesions in several series, including a retrospective study Jenson and colleagues ($n = 92$) and a prospective study by Lamprecht and colleagues ($n = 112$). Diagnostic yield has also been found to be significantly higher in patients with a bronchus sign compared the absence of a bronchus sign. In a study by Seijo and colleagues, overall diagnostic yield using ENB was 67% (34 of 51 procedures). A diagnosis was obtained in 30 of 38 lesions (79%) with a bronchus sign and 4 of 13 (31%) without a bronchus sign. In a study by Balbo and colleagues, ENB was diagnostic in 25 of 32 patients (78%) with a bronchus sign and 4 of 9 (44%) without a bronchus sign. The overall diagnostic yield of ENB was 70.7% (29 of 41 cases).



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Section Summary:

The evidence on ENB for diagnosis of pulmonary lesions is insufficient. 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. 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 are less data on the potential use of ENB in biopsy of mediastinal lymph nodes. Moreover, 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. The data are also insufficient to identify potential patient selection criteria. 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 of pulmonary lesions and mediastinal lymph nodes.

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

Three studies were identified; there were no RCTs. Only one of the trials compared fiducial marker placement with ENB to another method of fiducial marker placement. This study, by Kupelian and colleagues included 28 patients scheduled for radiation therapy 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 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.

A study by Anantham 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). Using the SuperDimension InReach 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.

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. 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



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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.

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 Guidelines and Position Statements

The 2014 National Comprehensive Cancer Network (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.

- 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 trans-thoracic needle aspiration (TTNA) is preferred.
- For patients with suspected nodal disease, EBUS, navigation biopsy or mediastinoscopy is preferred.

In 2013, the American College of Chest Physicians (ACCP) issued updated guidelines on the diagnosis of lung cancer. 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."

In 2011, the British Thoracic Society published a guideline on advanced diagnostic and therapeutic flexible bronchoscopy in adults. The guideline included the following recommendation: "Electromagnetic bronchoscopy may be considered for the biopsy of peripheral lesions or to guide TBNA for sampling mediastinal lymph nodes." This was a "Grade D" recommendation, meaning that it is based on non-analytic studies, e.g., case series or expert opinion, or based on extrapolated data from observational studies.

Summary

Electromagnetic navigation bronchoscopy uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. Overall, data are insufficient to determine the risks and benefits of ENB compared to standard approaches to diagnose peripheral lesions. 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; it is not clear whether this would be most appropriate as a



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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. Guidelines published in 2013 suggest ENB as an option for patients with peripheral lung lesions but these recommendations are not based on high-quality evidence demonstrating improved outcomes. Thus, use of this technology is considered investigational.

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Code Type	Code
CPT	31627
HCPCS	A4648
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	No codes

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01/07/2010 Medical Policy Committee approval
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 02/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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 02/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 02/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:



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