BlueCross BlueShield of Alabama

Name of Policy:
Electromagnetic Navigational Bronchoscopy

Policy #: 400
Category: Surgery
Latest Review Date: January 2014
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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 x-rays or chest CT scans. 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 6mm) 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 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. PET scans are also highly 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. 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.

Another proposed enhancement to standard bronchoscopy is Electromagnetic Navigation Bronchoscopy (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. There are three phases of a procedure using the InReach System, as follows:

1. Planning phase: This consists of loading previously taken CT scans onto a laptop computer, and using proprietary software 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 towards the target and the realtime 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 session. 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.

In September 2004, the superDimension/Bronchus (superDimension Ltd, Herzliya, Israel) 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, does not make a diagnosis and is not approved for pediatric use. The trade name of the device is the inReach™ System; it is currently marketed in the United States by superDimension, Inc, Minneapolis, MN. An updated catheter system (Edge™) for use with the InReach system was cleared by the FDA through the 510(k) process in October 2010. In May 2012, superDimension was acquired by Covidien (U.S. 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 virtual bronchoscopic navigation (VPN) system (Emergo Group, Austin, TX)

Policy:

Electromagnetic navigation bronchoscopy does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** for use **with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes.**

Electromagnetic navigation bronchoscopy does not meet Blue Cross and Blue Shield of Alabama's medical criteria and is considered **investigational** for the **placement of fiducial markers.**

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

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

ENB for the diagnosis of pulmonary lesions and mediastinal lymph nodes
Evaluation of electromagnetic navigation bronchoscopy with the InReach system 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 control trial using electromagnetic navigation bronchoscopy (ENB). 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 session, 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 biopsies 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 + 6mm.

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 negative predictive value 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.

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 five 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%.

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. 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 three 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 two 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. ENB was 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 eight complications: three cases of moderate bleeding (none required transfusion), three cases of pneumothorax (none required treatment), one case of hematoma (did not require treatment), and one 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 solitary pulmonary nodules without evidence of endobronchial pathology. The mean size of the targeted lesions was 24 + 8 mm. ENB yielded a definitive diagnosis in 52 lesions, and another ten 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 two 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%). 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 four 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% (five 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 colleauges, 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 four of nine (44%) without a bronchus sign. The overall diagnostic yield of ENB was 70.7% (29 of 41 cases).

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.

ENB 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.

Three studies were identified; there were no randomized controlled trials. Only one of the trial compared fiducial marker placement with ENB to another method of fiducial marker placement. Kupeliand et al included 28 patients scheduled for radiation therapy for early stage lung cancer. Follow-up data were available for 23 patients, 15 had markers placed transcutaneously under CT or fluoroscopic guidance and eight patients had markers placed transbronchially using the duper Dimension 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; eight of 15 patients with transcutaneous placement developed pneumothorax,

sic of which required chest tubes. In contrast, none of the eight patients with transbronchial placement developed pneumothorax.

Ananthan et al included nine patients with peripheral lung tumors who were considered nonsurgical candidates and were scheduled to undergo treatment with robotic stereotactic radiosurgery. Using the SuperDimension system, 39 fiducial markers were successfully placed in eight of the nine patients. A total of 35 of the 39 markers were still in place at radiosurgery planning seven to ten days later. No complications were observed. Both of these studies involved small sample sizes and were essentially feasibility studies; neither reported on the clinical outcomes after tumor treatment.

In 2010, Schroeder et al 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 five 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 seven 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.

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

Summary

Electromagnetic navigation bronchoscopy (ENB) uses computed tomography (CT) scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. Overall, there are insufficient data 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 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.

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 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.

Key Words:

Bronchoscopy, electromagnetic navigation, InReach, SuperDimension, ENB, Veran, IG4, SPiN Drive

Approved by Governing Bodies:

In September 2004, the superDimension/Bronchus (superDimension Ltd, Herzliya, Israel) was cleared for marketing by the FDA through the 510(k) process. The trade name of the device is the inReach™ System.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

Effective for dates of service on or after January 1, 2010:

31627 ;with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure)

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Policy History:

Medical Policy Group, December 2009 **(3)**
Medical Policy Group, January 2010 **(3)**
Medical Policy Administration Committee, January 2010
Available for comment January 26-February 22, 2010
Medical Policy Group, February 2010 **(3)**
Medical Policy Administration Committee, February 2010
Available for comment February 23-April 8, 2010
Medical Policy Group, March 2011
Medical Policy Group, February 2012 **(3)**: Updated Key Points & References,
Medical Policy Panel, January 2013.
Medical Policy Group, January 2013 **(3)**: Updated Description, Key Points & References. Policy statement remains unchanged.
Medical Policy Panel, January 2014
Medical Policy Group, January 2014 **(3)**: Update to Key Points & References; no change in policy statement
Medical Policy Group, May 2014 **(3):** Removed Code 31626 from Coding Section. Placed there in error.
Medical Policy Group, June 2014 **(3):** Updated policy with link to CareCore National© medical policies effective August 1, 2014
Medical Policy Administration Committee, June 2014
Available for comment June 16 through July 31, 2014

Medical Policy Group, July 2014: Removed CareCore link. Transfer to CareCore is on hold until further notice. The policy has been returned to FINAL.
