Electromagnetic Navigation-guided Bronchoscopy

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers electromagnetic navigation-guided bronchoscopy for the management of peripheral lung lesions experimental and investigational because of insufficient evidence of its effectiveness.

Background

The main problem in early diagnosis of lung cancer is the ability to reach small lung lesions and obtain diagnostic tissue samples. More than 50% of lung targets are not accessible by conventional bronchoscopes due to the diameter relative to the constantly narrowing branches of the bronchial tree and due to orientation and maneuverability difficulties (Rivera et al, 2003; Alberts and Colice, 2003). Average diagnostic yield for peripheral lung lesion biopsy performed with conventional flexible bronchoscopy is reported to be 69% for peripheral lesions greater than 20 mm, 33% for peripheral lesions less than 20 mm, and 50% to 85% for lymph nodes (Mazzone et al, 2002; Rivera et al, 2003; Schriebner and McCrory, 2003). Non-diagnostic bronchoscopy leads to more invasive interventions, such as transthoracic needle aspiration, mediastinoscopy or even thoracotomy.
Electromagnetic navigational bronchoscopy (ENB) was designed to increase the range of lung sites accessible by transbronchial needle aspiration, particularly in peripheral lesions. The bronchoscope and bronchial tool are guided on a path indicated by computed tomography (CT). Examples of ENB systems and accessories include, but may not be limited to: SPiN Drive; and superDimension Bronchus System (also known as the i-Logic System).

When ENB is used for diagnostic purposes, CT scans are first collected and downloaded into the system’s software, which reconstructs the scans into three-dimensional images of the lungs. The individual is sedated and positioned over an electromagnetic location board and bronchoscopy is initiated. A microsensor probe is inserted through the working channel of the bronchoscope into the airways. The sensor automatically registers the points and maps the appropriate route to peripheral lung lesions using the combined CT images and computer software. To navigate, the physician views the computer monitor and advances the guide to reach suspicious peripheral lung lesions. Tools can be inserted through the working channel to the lesion to collect samples.

It is also suggested that ENB may be used to enable marker placement within soft lung tissue. Fiducial markers are gold seeds or stainless steel screws that are implanted in and/or around a soft tissue tumor or within the bony spine, to act as a radiologic landmark to more precisely define the target lesion’s position. Fiducial markers may be placed using CT, endoscopic or surgical guidance.

In 2004, the Food and Drug Administration cleared for marketing through the 510(k) process the superDimension/Bronchus system, also known as the inReach system (superDimension, Ltd, Israel), a minimally invasive image-guidance localization and navigation system that uses electromagnetic guidance for the management of peripheral lung lesions. The system consists of several components: a guide catheter, a steerable navigation catheter, and planning and navigation software and hardware (i.e., computer and monitor). Navigation is facilitated by an electromagnetic tracking system that detects a position sensor incorporated into a flexible catheter advanced through a bronchoscope. Information obtained during bronchoscopy is super-imposed on previously acquired computed tomography (CT) data and 3-dimensional virtual images. The system was designed to solve the clinical problem of reaching small suspected lesions in the peripheral lung airways and mediastinal lymph nodes and is being proposed as an alternative to open surgical biopsy of distant lung lesions and as an alternative to transthoracic implantation of radiosurgical markers.

Hautmann et al (2005) assessed the usability, accuracy, and safety of electromagnetic navigation during flexible bronchoscopy in a clinical setting. Sixteen patients (10 men and 6 women; mean age of 63.7 years) referred to a bronchoscopy unit for the diagnosis of peripheral infiltrates or...
solitary pulmonary nodules (SPNs) were studied using an electromagnetic tracking system with a position sensor encapsulated in the tip of a flexible catheter that was pushed through the working channel of the bronchoscope. Real-time, multiplanar reconstruction of a previously acquired CT data set provided 3-dimensional views for localization of the catheter. To match the position of the sensor with the CT scan, four anatomic landmarks were used for registration. The sensor position generated in the navigation system was controlled by fluoroscopy, and the corresponding error distances were measured. This was performed with all SPNs and at 2 different peripheral locations of the right upper lobe (RUL). Navigation prolonged bronchoscopy by 3.9 +/- 1.3 mins. The navigation system identified all lesions. The position sensor achieved a direct hit in 3 of 5 SPNs. Fluoroscopy failed to recognize 3 SPNs (60 %) and 3 infiltrates (38 %). The mean error distances between sensor tip position and fluoroscopically verified RUL reference position were 10.4 mm (lateral position) and 12.5 mm (apical position), respectively. The mean error distances between the sensor tip and 2 endobronchial registration points at the end of the procedure were 4.2 mm and 5.1 mm, respectively. The authors concluded that electromagnetic navigation is useful, accurate, and safe in the localization of peripheral lung lesions and may help to improve the yield of diagnostic bronchoscopic procedures.

In a prospective, open label, single-center, pilot study, Gildea and colleageaus (2006) investigated the safety and efficacy of the superDimension/Bronchus system for sampling peripheral lung lesions and mediastinal lymph nodes with standard bronchoscopic instruments. The final distance of the steerable probe to lesion, expected error based on the actual and virtual markers, and procedure yield was gathered on 60 subjects enrolled between December 2004 and September 2005. Mean navigation times were 7 +/- 6 mins and 2 +/- 2 mins for peripheral lesions and lymph nodes, respectively. The steerable probe tip was navigated to the target lung area in all cases. The mean peripheral lesions and lymph nodes size was 22.8 +/- 12.6 mm and 28.1 +/- 12.8 mm, respectively. The diagnostic yield was 74 % for peripheral lesions and 100 % for lymph nodes. A diagnosis was obtained in 80.3 % of bronchoscopic procedures. A definitive diagnosis of lung malignancy was made in 74.4 % of subjects. Pneumothorax occurred in 2 subjects. The authors concluded that electromagnetic navigation bronchoscopy is a safe method for sampling peripheral and mediastinal lesions with high diagnostic yield independent of lesion size and location.

Other studies that have evaluated electromagnetic navigation bronchoscopy have evaluated its diagnostic yield. There are few studies that have directly compared electromagnetic navigation bronchoscopy to other techniques to improve the diagnostic yield of bronchoscopy, and there are no studies examining the impact of electromagnetic navigation bronchoscopy on clinical decisionmaking, patient management, or clinical outcomes.
Becker et al (2005) reported on the diagnostic yield with electromagnetic navigation bronchoscopy of 69% in 29 patients with isolated peripheral lung lesions. After reaching the lesion, fluoroscopy was performed to confirm that the sensor probe had reached the target. Then an ultrasound probe was passed through an extended working channel to visualize the lesions. Biopsies were obtained after confirmation with fluoroscopy and endobronchial ultrasound. Nine of the biopsies (31%) were false-negatives as proved by surgical biopsy.

Makris et al (2007) prospectively evaluated the diagnostic yield and safety of electromagnetic navigation-guided bronchoscopy biopsy for small peripheral lung lesions in patients where standard techniques were non-diagnostic. The study was conducted in a tertiary medical center on 40 consecutive patients considered unsuitable for straight-forward surgery or CT-guided transthoracic needle aspiration biopsy, due to co-morbidities. The lung lesion diameter was 23.5 +/- 1.5 mm and the depth from the visceral-costal pleura was 14.9 +/- 2 mm. Navigation was facilitated by an electromagnetic tracking system. Divergence between CT data and data obtained during bronchoscopy was calculated by the system's software as a measure of navigational accuracy. All but one of the target lesions was reached and the overall diagnostic yield was 62.5%. Diagnostic yield was significantly affected by CT-to-body divergence with the reported yield increasing to 77.2% when estimated divergence was less than or equal to 4 mm. Three pneumothoraxes occurred and chest drainage was required in 1 case. The authors concluded that electromagnetic navigation-guided bronchoscopy has the potential to improve the diagnostic yield of transbronchial biopsies without additional fluoroscopic guidance, and may be useful in the early diagnosis of lung cancer, particularly in non-operable patients.

Eberhardt et al (2007a) prospectively collected data to determine the yield of electromagnetic navigation-guided bronchoscopy without fluoroscopy in the diagnosis of peripheral lung lesions using the superDimension/Bronchus system. Fluoroscopy was not utilized, but post-transbronchial biopsy chest radiographs were obtained to exclude pneumothorax. The primary end point was diagnostic yield, and the secondary end points were navigation accuracy, procedure duration, and safety. Analysis by lobar distribution was also performed to assess performance in different lobes of the lung. Ninety-two peripheral lung lesions were biopsied in 89 subjects. The diagnostic yield of electromagnetic navigation-guided bronchoscopy was 67%, which was independent of lesion size. Total procedure time ranged from 16.3 to 45.0 mins. The mean navigation error was 9 +/- 6 mm (range, 1 to 31 mm). There were 2 incidences of pneumothorax for which no intervention was required. When analyzed by lobar distribution, there was a trend toward a higher electromagnetic navigation-guided bronchoscopy yield in diagnosing lesions in the right middle lobe (88%). The authors reported that electromagnetic navigation-guided bronchoscopy did not compromise the diagnostic yield or increase the risk of pneumothorax and may result in sizable time saving and reduction in radiation exposure.
In a prospective trial, Eberhardt et al (2007b) assessed the diagnostic yield of the super Dimension Bronchus system in pulmonary nodules less than 30 mm and compared the difference in tissue sampling techniques. Fifty-four patients (14 women, 40 men) underwent superDimension/Bronchus guided bronchoscopy during which one peripheral lung lesion was navigated to and biopsied twice. Primary end-point was the diagnostic yield of electromagnetic navigation-guided bronchoscopy without additional use of fluoroscopy. Other parameters, including tissue sampling modality, procedure time, distance to targeted lesion, lesion parameters (e.g., size and location), were also collected. Patients were followed until the definitive diagnosis was obtained and/or the diagnosis was verified by another technique. Thirty-nine of 54 patients (72.2 %) were diagnosed correctly (definitive histology or benign results that were confirmed with follow-up) with the super Dimension Bronchus technique. The mean lesion size was 23.3 mm ranging from 14 mm to 29 mm. Mean navigation duration was 3.5 mins (ranging from 0.3 to 14 mins). Sampling method of catheter suction was more successful than the forceps biopsy. One pneumothorax occurred (1.92 %), which was small and no intervention was necessary. The authors concluded that the super Dimension Bronchus technique was a safe diagnostic approach that increases significantly the diagnostic yield of peripheral lung lesion biopsies compared with standard bronchoscopy and can be used to obtain histological diagnosis in peripheral lung lesions.

Eberhardt et al (2007c) reported on a prospective randomized study that compared the diagnostic yield of electromagnetic navigation bronchoscopy, endobronchial ultrasound and a combined procedure in 120 patients with peripheral lung lesions or solitary lung nodules on CT scans. Endobronchial ultrasound was performed without fluoroscopic guidance. In the combined procedure, after electromagnetic navigation, an ultrasound probe was passed through an extended working channel to visualize the lesion. The reference gold standard was histologic diagnosis on transbronchial lung biopsy, or surgical biopsy if the transbronchial lung biopsy failed to yield a definitive histological diagnosis. The investigators found that electromagnetic navigation bronchoscopy had a lower diagnostic yield (59 %) than endobronchial ultrasound (69 %). However, the combined procedure had a higher diagnostic yield (88 %) than either procedure alone. The investigators found significantly diminished diagnostic yield (29 %) in the lower lobes with electromagnetic navigation bronchoscopy. The investigators posited that navigation in the lower lobes may be more affected by diaphragmatic movement during breathing. They explained that this is because the planning data are based on CT images acquired in a single breath hold and cannot compensate for respiratory movements.

Wilson and Bartlett (2007) reported on the diagnostic yield of electromagnetic navigation bronchoscopy with rapid on-site cytologic evaluation of tissue samples. The records of 248 consecutive patients that had electromagnetic navigation bronchoscopy were retrospectively reviewed to determine the diagnostic yield. The investigators reported a diagnostic yield of 70 %
when all inconclusive cases were treated as nondiagnostic. The investigators concluded that "prospective studies with longer clinical follow-up, and studies of the impact of EMN [electromagnetic navigation] and ROSE [rapid on-site cytological evaluation] use on clinical decision making, patient management, and patient outcomes are needed to further elaborate the value of our data."

Guidelines from the American College of Chest Physicians on evaluation of patients with pulmonary nodules (Gould et al, 2007) commented on electromagnetic navigation bronchoscopy, but made no specific recommendations for its use: "A newer technique, electromagnetic navigation, combines simultaneous CT virtual bronchoscopy with real-time fiberoptic bronchoscopy and shows promise as another tool for guiding biopsy of peripheral nodules. Although these new methods seem to improve diagnostic yields over fluoroscopic guidance, results still do not compare favorably with those from a recent series that evaluated TTNA [transthoracic needle aspiration] in patients with small peripheral nodules."

Krishna and Gould (2008) stated that newer minimally invasive techniques should be rigorously evaluated for their role in the diagnostic algorithm of peripheral lung lesions. Electromagnetic navigation-guided bronchoscopy is a promising minimally invasive method of reaching distant lung lesions, however, long-term studies with larger sample sizes are required to define its role in the diagnostic pathway for lung cancer and management of peripheral lung lesions.

Furthermore, a technology assessment on electromagnetic navigation bronchoscopy by the VA Boston Healthcare System (2008) concluded that the data are insufficient to determine whether the use of electromagnetic navigation bronchoscopy will avoid surgical biopsy procedures in surgical candidates because of its low negative predictive value. An earlier evaluation by CEDIT (2006) concluded that electromagnetic navigation bronchoscopy is promising but as yet insufficiently validated.

An assessment by the Canadian Agency for Drugs and Technologies in Health (Cimon and Argáez, 2008) found 1 randomized controlled trial and 10 observational studies on electromagnetic navigation systems for bronchoscopy. No health technology assessments, systematic reviews, meta-analyses, economic analyses, or evidence-based guidelines were identified.

Eberhardt et al (2010) stated that although the treatment of choice for stage I lung cancer patients is surgery, a lot of patients have a high co-morbidity and are medically inoperable. Bronchoscopy, as a central technique in diagnosing lung cancer, has the potency to apply endoscopic therapy to small lung lesions in a minimally invasive way in patients with high-risk for surgery. Unfortunately, bronchoscopy can not always reach lesions in the peripheral lung, in
particular the smaller lesions. Therefore, new guidance techniques like virtual bronchoscopy and electromagnetic navigation are now available and instead of using the systems as a diagnostic tool, these techniques may provide an option for therapeutic interventions to patients with inoperable lung. With endoscopic fiducial marker placement for robotic radiosurgery and endoluminal high-dose brachytherapy, local radiotherapy of peripheral lung tumors becomes feasible, reducing radiotherapy-induced toxicity. Radiofrequency tissue ablation through the working channel of a flexible bronchoscope may offer diagnosis and curative treatment in one endoscopic session. However, technical improvements of the ablation probes are needed to expand the sizes of ablated areas. Even though the technologies are very attractive and pilot data are extremely encouraging, more studies establishing selection criteria and best utility are needed.

A meta-analysis by Wang et al (2012) reported that electromagnetic navigational bronchoscopy had a lower diagnostic yield (67 %) than the pooled average of all of the guided bronchoscopy technologies included in the analysis (pooled diagnostic yield of 70 %).

The British Thoracic Society guidelines for advanced diagnostic and therapeutic flexible bronchoscopy in adults (Du Rand et al, 2011) listed electromagnetic navigation bronchoscopy as one of the emerging applications for flexible bronchoscopy. The guidelines noted that electromagnetic bronchoscopy may be considered for the biopsy of peripheral lesions or to guide trans-bronchial needle aspiration for sampling mediastinal lymph nodes (grade D). A grade "D" recommendation is based on evidence level 3 or level 4, or extrapolated evidence from studies rated as 2+ (level 3 refers to non-analytic studies, e.g., case reports, case series; level 4 refers to expert opinion; and level 2+ refers to well-conducted case-control or cohort studies with a low-risk of confounding, bias or chance, and a moderate probability that the relationship is causal).

Guidelines from the American College of Chest Physicians (2013) listed electromagnetic navigation bronchoscopy as an emerging technology for the diagnosis of lung cancer, and that it shows the potential for increasing the diagnostic yield of flexible bronchoscopy for diagnosis of peripheral lung lesions (grade 1C recommendation based upon low or very low quality evidence - observational studies or case series). ACCP guidelines for the evaluation of lung lesions state that electromagnetic navigation bronchoscopy shows promise as another tool for guiding biopsy of peripheral nodules. The ACCP literature review identified 10 studies that reported the sensitivity of ENB-guided TBB for the identification of malignancy in peripheral lung lesions, including four studies that described results for nodules measuring less than 2 cm. Among the latter studies, diagnostic yield ranged from 44 % to 75 % (median of 68.5 %). Across all 10 studies, the risk of pneumothorax ranged from 0 % to 7.5 % (median of 2.2 %). ACCP guidelines stated that studies were limited by small sample sizes, uncertain representativeness of the study populations, and retrospective uncontrolled design.
Chenna and Chen (2014) stated that peripheral pulmonary lesions are an increasingly common finding in clinical practice. While many nodules are followed with radiographic surveillance, some may require biopsy. Conventional bronchoscopy with trans-bronchial lung biopsy has traditionally performed poorly for small, peripheral lesions, and TTNA with CT guidance has been favored as the diagnostic test of choice. Despite the high diagnostic yield of TTNA, procedural complications such as pneumothorax continue to be problematic. New technology has been developed to improve the diagnostic yield of bronchoscopy for peripheral lesions over conventional methods, while maintaining the favorable safety profile of a bronchoscopic approach. Virtual bronchoscopy and electromagnetic navigation are CT-based image guidance systems that create virtual bronchoscopic representations of the trachea-bronchial tree to assist the bronchoscopist in locating peripheral lesions. Radial probe endobronchial ultrasound utilizes real-time ultrasound to confirm the location of peripheral lesions before biopsy. The authors summarized the technical platforms, procedures, and clinical evidence for these emerging technologies.

Arias and colleagues (2015) stated that lung nodule evaluation represents a clinical challenge especially in patients with intermediate risk for malignancy. Multiple technologies are available to sample nodules for pathological diagnosis. Those technologies can be divided into (i) bronchoscopic and (ii) non-bronchoscopic interventions. Electromagnetic navigational bronchoscopy is being used for the endo-bronchial approach to peripheral lung nodules; but this approach has been hindered by anatomic challenges resulting in a 70% diagnostic yield. Electromagnetic navigational guided transthoracic needle lung biopsy is a novel, non-bronchoscopic method that uses a percutaneous electromagnetic tip tracked needle to obtain core biopsy specimens. Electromagnetic navigational transthoracic needle aspiration complements bronchoscopic techniques potentially allowing the provider to maximize the diagnostic yield during one single procedure. These investigators described a novel integrated diagnostic approach to pulmonary lung nodules. They proposed the use of endo-bronchial ultrasound trans-bronchial needle aspiration (EBUS-TBNA) for mediastinal staging; radial EBUS, navigational bronchoscopy and electromagnetic guidance trans-thoracic needle aspiration (ETTNA) during one single procedure to maximize diagnostic yield and minimize the number of invasive procedures needed to obtain a diagnosis. The authors stated that additional clinical studies are needed to determine the clinical utility of this novel technology.

An UpToDate review on “Image-guided bronchoscopy for biopsy of peripheral pulmonary lesions” (Shepherd, 2016) states that “Although large randomized trials are lacking, ENB [electromagnetic navigation bronchoscopy] has a similar yield to other IGB techniques, ranging from 44 to 75% (average approximately 65%). Most trials utilized the same commercially available system and analysis is limited by methodological flaws including retrospective design, small sample size, and variations in IGB techniques employed to biopsy nodules of varying size.
and location … A pilot study of a different system is limited to a single report in 24 patients undergoing lymph node sampling for lung cancer staging that compared electromagnetic-guided transthoracic needle aspiration (ETTNA) with other navigational systems and/or EBUS. The overall diagnostic yield for the techniques tested was 72 % (NB alone), 83 % (ETTNA alone), 87 % (NB plus ETTNA), and 97 % (ETTNA plus NB plus EBUS). Additional larger studies will be needed to further evaluate this ENB/TTNA system.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".

| Code   | Code Description                                           |
|--------|-----------------------------------------------------------|
| CPT codes not covered for indications listed in the CPE |
| There are no specific codes for Electromagnetic Navigation-hyperphyenguided Bronchoscopy |
| ICD-10 codes not covered for indications listed in the CPE |
| R91.1  | Solitary pulmonary nodule                                 |
| R91.8  | Other nonspecific abnormal finding of lung field          |

The above policy is based on the following references:

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Amendment to
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Electromagnetic Navigation-guided Bronchoscopy

There are no amendments for Medicaid.