



Cigna Medical Coverage Policy

**Subject Electromagnetic Navigation
Bronchoscopy**

Effective Date 7/15/2014
Next Review Date 6/15/2015
Coverage Policy Number 0492

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Coverage Policy

Cigna does not cover electromagnetic navigation bronchoscopy for any indication because it is considered experimental, investigational or unproven.

General Background

Lung cancer may be suspected in individuals who have an abnormal chest radiograph finding or have symptoms caused by local or systemic effects of the tumor. The diagnostic method depends on the type of lung cancer suspected, the suspected location of the primary tumor, presence of metastasis, and the patient's overall clinical status. Traditional flexible bronchoscopy is a common, minimally invasive method to collect tissue from suspicious lesions for histological analysis. Bronchoscopy is an effective tool for sampling central airway lesions, mediastinal nodes, and parenchymal masses, but is less effective for peripheral lung lesions. The sensitivity of bronchoscopy for diagnosing central endobronchial lesions is 88%, compared to 34% for peripheral lesions smaller than two centimeters in diameter, and 63% for peripheral lesions larger than two centimeters. In evaluating peripheral lung lesions, the diagnostic yield of bronchoscopy with standard fluoroscopic guidance is improved when performed with CT or endobronchial ultrasound (EBUS) guidance. EBUS allows direct visualization of the target lesion prior to attempting biopsy. Even when these adjunctive procedures are employed, however, the ability of flexible bronchoscopy to reach peripheral lesions is limited. Biopsy of peripheral lesions may be performed by transthoracic needle aspiration (TTNA), which relies on using images from CT or fluoroscopy to direct the biopsy needle through the skin and into the lesion. A drawback of this procedure is the risk of pneumothorax. The risk of pneumothorax with transthoracic needle aspiration has been estimated at 22–45%.

Electromagnetic navigation bronchoscopy (ENB) has been proposed as a method to further increase the diagnostic yield of flexible bronchoscopy in the diagnosis of peripheral and mediastinal lung lesions by allowing the physician to place endobronchial accessories (e.g., forceps, brush, needle) in areas of the lung that would be hard to reach otherwise. ENB combines simultaneous CT virtual bronchoscopy with real-time fiberoptic bronchoscopy. Researchers have proposed that ENB has the potential to contribute to the early diagnosis and treatment of lung cancer. ENB has also been proposed for placement of dye markers in peripheral lung lesions and near the pleura surface in order to provide guidance during video-assisted thoracoscopic surgery, and for placement of radiosurgical markers transbronchially to help radiation oncologists plan and treat patients with external beam radiation (ECRI, 2010; Gould, 2007; Mason, 2005; Rivera and Mehta, 2007).

The inReach™ System, currently referred to as the iLogic™ System (superDimension, Inc., Minneapolis, MN) received U.S. Food and Drug Administration approval in 2004. A second system, ig4™ EndoBronchial (Veran Medical Technologies, Inc., St. Louis MO), considered to be substantially equivalent to the inReach System, received 510(k) approval in 2009 (see below). With the iLogic system, anatomical data from a computed tomography (CT) scan taken prior to the procedure is imported into the planning laptop, and the software generates a three-dimensional image of the patient's lungs. The physician uses the virtual and CT images to plan the path the catheters will follow in the bronchial tree. Electromagnetic navigation is therefore not a real-time system; the procedure is based on the reconstructed positioning as generated by the computerized system from the pre-procedure CT scan. Because there could be slight movement during the procedure, lesions observed in the pre-procedure CT scan may not appear in the same location during the bronchoscopy.

During the ENB procedure, the patient is positioned over an electromagnetic board, and a microsensor probe is inserted through the working channel of the bronchoscope into the airways. Three-dimensional images are generated from computed tomography (CT) scans taken preoperatively. The sensor's movements and position are overlaid in real time onto the virtual three-dimensional image of the lungs, allowing the physician to navigate into previously inaccessible areas of the lungs. The procedure is generally performed with the patient under conscious sedation, and takes 5–20 minutes.

Researchers have proposed that ENB has the potential to contribute to the early diagnosis and treatment of lung cancer. There is insufficient evidence in the published peer-reviewed medical literature, however, to demonstrate the safety and efficacy of this procedure, or to determine the diagnostic accuracy of this method compared to currently available biopsy techniques, including transthoracic needle aspiration or flexible bronchoscopy combined with multiplanar computed tomography (CT) or endobronchial ultrasound. There is insufficient evidence to demonstrate that ENB impacts treatment of lung cancer or results in improved rates of survival. In addition, invasive diagnostic or therapeutic treatment may still be indicated if results obtained using this method are non-diagnostic or are positive for cancer. Electromagnetic navigation bronchoscopy would therefore not necessarily obviate the need for subsequent surgical intervention. ENB is also being evaluated for the placement of dye markers in peripheral lung lesions to provide guidance during video-assisted thoracoscopic surgery, and for placement of radiosurgical markers in preparation for treatment with external beam radiation. There is insufficient evidence in the peer reviewed medical literature to establish the safety and clinical utility of ENB for these indications.

U. S. Food and Drug Administration (FDA)

inReach™ System (superDimension, Inc., Minneapolis, MN): The inReach System received FDA approval through the 510(k) process on November 8, 2004, with subsequent approvals for modifications to the product and its components. The 510(k) approval summary states that the device is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. The summary notes that the device does not make a diagnosis, is not an endoscopic tool, and is not intended for pediatric use. The most recent 510(k) summary (September 4, 2009) includes software changes and minor changes to the personal and laptop computer. According to the superDimension website, the system is currently marketed as iLogic™ Electromagnetic Navigation Bronchoscopy™. SuperDimension was acquired by Covidien, Inc., Mansfield, MA, in 2012.

The inReach™ /iLogic™ System consists of four components; a disposable guide catheter that extends beyond the reach of the bronchoscope and becomes an extended channel for endobronchial tools to distal locations in the lungs; a steerable navigation catheter that contains a location sensor at the distal tip to allow steerability through the bronchial tree; planning and navigation software that provides a reconstruction of the bronchial

airways; and hardware, including a localization system, computer and monitor, that provides the physician with real-time catheter positioning within the lungs.

ig4™ EndoBronchial (Veran Medical Technologies, Inc., St. Louis MO): The ig4 EndoBronchial received FDA approval through the 510(k) process on December 2, 2009. According to the 510(k) summary, the device was shown to be substantially equivalent to the inReach System for its intended use of navigating endoscopic tools, catheters, and guidewires in the pulmonary tract, and substantially equivalent to the ig4 Image Guided System in automatic 3D registration to a CT-based model of the lungs and navigation of instruments. The Ig4 is an accessory for a CT system that utilizes electromagnetic tracking technology to locate and navigate endoscopic tools, catheters, and guidewires relative to a CT-based model of the tracheobronchial tree. The system incorporates a method of gating the location information on soft tissue to the patient's respiration. The ig4 System consists of an electromagnetic tracking accessory, a patient referencing system, an electromagnetic field generator and tracking system, software, a computer system, and a pulmonary planning workstation. The electromagnetic tracking accessory consists of a navigation guidewire and may include additional navigated endoscopic tools.

The ig4 System is intended for use in clinical interventions and for anatomical structures where CT and/or endoscopic bronchoscopy are currently used for visualizing such procedures. The system compensates for the patient's respiratory phases. It is indicated for displaying:

- An interventional instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays a CT-based model of the target organ(s).
- A CT-based model of the lungs and images of the tracheobronchial tree to aid a physician in guiding endoscopic tools, catheters or guidewires in the pulmonary tract.

According to the Veran Medical Technologies website, ig4 EndoBronchial is being marketed as the SPiN™ Drive System.

Literature Review

Electromagnetic Navigation Bronchoscopy for the Diagnosis of Lung Lesions:

Gex et al. (2014) conducted a systematic review and meta-analysis to describe ENB's yield and safety profile for peripheral lung lesions (1033 lung nodules, 15 studies). A positive and definitive diagnosis was obtained after 64.9% of all ENB procedures (95% CI 59.2-70.3). Overall diagnostic accuracy was 73.9% (95% CI 64.6-76.8). Sensitivity to detect cancer was 71.1% (95% CI 64.6-76.8), with a negative predictive value of 52.1% (95% CI 43.5-60.6). The rate of pneumothorax was 3.1%. Several studies relied on additional techniques and strategies, including fluoroscopy, endobronchial ultrasound (EBUS), radial probe, rapid on-site cytological evaluation (ROSE) and general anesthesia. The methodological quality of the studies included in the meta-analysis was poor. Selection criteria were rarely clear enough to allow reproducibility, especially regarding choice of diagnostic procedure or why ENB rather than another technique or surgical resection was performed. It was not possible to assess selection bias, since in all studies it was unclear whether the study subjects were representative of patients who would undergo ENB sampling in actual practice.

Wang et al., (2012) conducted a meta-analysis to determine the overall diagnostic yield of guided bronchoscopy using one or a combination of the following: ENB, virtual bronchoscopy (VB), radial endobronchial ultrasound (R-EBUS), ultrathin bronchoscope, and guide sheath. The analysis included 39 studies/3052 lesions. The pooled diagnostic yield was 70%, which is higher than the yield for traditional transbronchial biopsy. The yield increased as the lesion size increased. Three modalities had a higher diagnostic yield than the overall yield: VB, R-EBUS, and the use of a guide sheath. The authors noted that VB had a higher weighted diagnostic yield than ENB, despite the fact that ENB has a VB component that is simulated prior to the bronchoscopy, and ENB has real-time navigation, potentially making it more accurate. Yet the yield of ENB was less than VB alone. They suggested that this variance may depend on the operator and the software that generates the virtual picture. The authors concluded that guided bronchoscopy may be an alternative or be complementary to transthoracic needle aspiration for tissue sampling of pulmonary nodules, but further study is needed to determine its role in the evaluation of peripheral pulmonary lesions.

In a nonrandomized comparison, Loo et al (2014) (n=40 patients, 50 peripheral lung lesions) reported a diagnostic yield range of 61% to 95% from use of superDimension with positron emission tomography-CT, rapid on-site evaluation (ROSE), ENB-guided transbronchial biopsy, or ENB-guided bronchial brushing. Overall

sensitivity was $\pm 85\%$, and overall specificity was $\pm 96\%$. Sensitivity and diagnostic yield were lower in diagnostic cohort studies published by Odrionic et al. (2014) (n=91 patients, 95 ENB-guided FNAs) and Chee et al. (2013) (n=60 patients). Odrionic et al. reported a sensitivity rating of 63% for ENB-guided FNA to detect malignancy, while Chee et al. reported a diagnostic yield of 50% using ENB with superDimension plus peripheral endobronchial ultrasound (pEBUS). Use of ENB did improve the localization of lung lesions, however; the diagnostic yield of pEBUS alone was 43%.

A case series conducted by Lamprecht et al. (2011) evaluated factors associated with the diagnostic yield of electromagnetic bronchoscopy (ENB). The diagnostic work-up for 112 consecutive patients with a solitary pulmonary nodule included a fluorodeoxyglucose positron emission computed tomography (FDG-PET-CT) and ENB in combination with rapid onsite cytopathologic evaluation (ROSE). PET-CT has been shown to improve the diagnostic accuracy of the staging of non-small-cell lung cancer, but does not provide a definite tissue diagnosis. Tissue sampling is therefore still required to confirm a suspected malignancy. The final diagnosis was made by histopathological examination of the specimen obtained by ENB, or by CT-guided fine needle aspiration or surgery, if ENB was not diagnostic. In 83.9% of patients, the combination of PET-CT, ENB and ROSE established a correct diagnosis. The diagnostic yield was independent of the size of lesion, localization in the lungs, or lung function. A steep learning curve was observed, with a diagnostic yield of 80% for the first 30 procedures compared to 87.5% for the last 30 procedures.

Eberhardt et al. (2007) conducted a randomized controlled trial to evaluate the diagnostic yield of endobronchial ultrasound vs. electromagnetic navigation bronchoscopy (ENB) using the superDimension Bronchus vs. a combination of the two procedures (n=120). Patients with evidence of peripheral lung lesions or solitary pulmonary nodules on CT scan who were referred to a pulmonary interventional service were randomized to one of the three treatment groups. Of the 120 patients, two patients with a non-diagnostic bronchoscopy declined surgical biopsy and were excluded from the analysis. The diagnostic yield of the combined procedure (endobronchial ultrasound plus ENB) was 88%, compared to 69% for endobronchial ultrasound alone, and 59% for ENB alone (p=0.02). The combined procedure yield was independent of lesion size or lobar distribution. There was a greatly diminished lower lobe yield (29%) in the ENB alone arm, attributed to navigation error. The planning data are based on CT images obtained during a single breath hold, with inability to compensate for respiratory movement. The overall rate of pneumothorax was 6%, with no significant difference across the three study arms. The authors attributed the improved diagnostic yield of the combined procedure to the ability of endobronchial ultrasound to directly visualize the internal structures of peripheral lung lesions with the precise navigation capability of ENB.

Makris et al. (2007) evaluated the diagnostic yield and safety of ENB using the superDimension/Bronchus for small peripheral lung lesions in a series of 40 consecutive patients considered unsuitable for straightforward surgery or CT-guided transthoracic needle aspiration biopsy. The primary efficacy endpoint was the ability of the procedure to diagnose lung cancer or other lung pathology. Patients underwent additional diagnostic procedures if ENB was inconclusive, and cases were considered to be non-diagnosed if any of these additional procedures resulted in diagnosis of lung cancer or lung pathology. ENB produced a diagnosis in 25 (62.5%) of 40 patients. In the remaining 15 cases, the procedure was either non-diagnostic (n=14) or not feasible (n=1). No significant correlation between the diagnostic yield of the procedure and the location of the lesion was observed. Divergence between CT data and data obtained during bronchoscopy was calculated by the system's software as a measure of navigational accuracy. Diagnostic yield was significantly affected by CT-to-body divergence; the yield was 77.2% when the estimated divergence was ≤ 4 millimeters, but was significantly lower when CT-to-body divergence was > 4 millimeters. The authors noted that CT-to-body divergence is unavoidable, since ENB is not a real-time system, and this may be one of the drawbacks. The diagnostic yield is based on the reconstructed positioning as generated by the computerized system from the pre-procedure CT data. The authors noted that the integrated navigation sensor and software improvements are necessary in order to improve navigational accuracy before this method is widely applied in clinical practice.

A prospective case series was conducted by Gildea et al. (2005) to determine the safety of electromagnetic navigation biopsy (ENB) with the superDimension/Bronchus system and the ability to sample peripheral lung lesions and mediastinal lymph nodes with standard bronchoscopic equipment (n=60). Enrolled patients were referred for presumed difficult bronchoscopy, prior non-diagnostic bronchoscopy, or with lesions traditionally not reachable by routine bronchoscopy. The procedure was completed in 58 of 60 patients. Total numbers of peripheral lesions and lymph nodes sampled were 56 and 31, respectively. Two patients with non-diagnostic ENB procedures did not complete follow-up and were not included in the analysis. A total of 56 cases, including

54 peripheral lesions and 31 lymph nodes, were therefore included in the analysis. Overall, a diagnosis was obtained in 80.3% (45 of 56) of procedures. A total of 74% (40 of 54) of procedures performed for peripheral lesions, and 100% (31 of 31) of lymph nodes were successfully sampled by ENB. A definitive diagnosis of lung cancer was made in 74.4% of patients. Diagnostic yield did not differ significantly based on lesion size or location. Pneumothorax occurred in two patients, and was not thought to be directly related to the ENB itself.

ECRI

An ECRI Emerging Technology Evidence Report, Electromagnetic Navigation (i-Logic System) During Flexible Bronchoscopy to Aid in Diagnosis of Peripheral Lung Lesions (2010), concluded that the quantity, quality, and consistency of the evidence base is low. None of the eight reviewed studies that reported diagnoses made using the superDimension ENB system, currently known as iLogic, provided information on the cancer diagnosis verified by a rigorous reference standard. Evidence is very limited for verified diagnostic yield of non-cancer diagnoses, and the studies provided no information on which specific benign diagnoses ultimately proved to be false negatives for cancer.

When the system was used to biopsy peripheral lung lesions, half of patients (range 46%–62% across studies) were diagnosed with histologically-confirmed cancer. If it is assumed that all cancer diagnoses are true positives, using the system would spare approximately half of all patients from more invasive diagnostic methods. However, additional testing or clinical follow-up was required in patients with inconclusive findings, and in most studies, to confirm benign findings. Most patients (60% overall, range 46%–80%) across studies who were found not to have cancer when the system was used were actually found to have cancer when other testing modalities were used. Follow-up testing of all patients without a histologic cancer diagnosis is therefore indicated. In terms of the safety profile, the authors stated that claims that the system avoids risk or has a comparable risk of pneumothorax relative to any other procedure for diagnosing these lesions is not supported by direct comparative evidence at this time.

Electromagnetic Navigation Bronchoscopy for Placement of Fiducial Markers:

Fiducial markers (e.g., coils or bands) are placed at or near the target lesion to guide future treatment, including stereotactic radiosurgery. Stereotactic radiosurgery may be considered in patients who are not candidates for lung cancer surgery. Modalities for placement of fiducial markers include transthoracic, intravascular and bronchoscopic. Bronchoscopic insertion has fewer side effects than the other modalities. Transthoracic CT-guided placement is associated with a significant risk of pneumothorax. Electromagnetic navigation has been proposed as a method to improve the accuracy of bronchoscopic placement of fiducial markers.

Schroeder et al. reported results of a case series evaluating fiducial marker placement using navigation bronchoscopy in inoperable patients with peripheral lung tumors (n=52). Of the 52 patients, four received 17 linear fiducial markers and 49 patients with 56 tumors received 217 coil-spring fiducial markers. The procedure was considered successful if the markers had been placed in or near the tumors and remained in place without migration, allowing CyberKnife stereotactic body radiosurgery without the need for additional markers. A total of 234 fiducial markers were successfully deployed in 52 patients with 60 tumors. Of these 60 tumors, 35 (58%) were adjacent to the pleura. During CyberKnife planning, 8 of 17 linear fiducial markers and 215 of 217 coil-spring fiducial markers were still in place (p=0001). Of the four patients with linear fiducial markers, two required additional fiducial placements. Pneumothorax occurred in three of the 52 patients; two were treated with a chest tube and one with observation.

Kupelian et al. (2007) conducted a small study to evaluate the transcutaneous placement of metallic fiducial markers under either CT or fluoroscopic guidance (n=15) compared to transbronchial placement with the superDimension/Bronchus system (n=8) in patients with small, early stage lung cancer. Pneumothorax occurred in 8 of 15 transcutaneous implants; six of these patients required chest tube placement. Pneumothorax did not occur in any of the patients who underwent transbronchial implantation. Marker stability was evaluated by observing the variation in gross target volume central point relative to the marker on repeat CT scans. The average three-dimensional variation in the gross target volume center relative to the marker was 2.6 ± 1.3 (SD) millimeters, and the largest variation along any anatomic axis for any patient was < 5 millimeters. The authors stated that although marker geometry can be affected by tumor shrinkage and deformation to some extent, implanted markers are stable throughout treatment regardless of the implantation method.

Professional Societies/Organizations

American College of Chest Physicians (ACCP): ACCP Evidence-Based Clinical Practice Guidelines, Diagnosis and Management of Lung Cancer, 3rd edition (Rivera et al., 2013) includes the following recommendations for pleural biopsy:

- In patients suspected of having lung cancer, if sputum cytology is done but is negative for carcinoma, it is recommended that further testing be performed (Grade 1C; strong recommendation, low quality evidence)
- In patients suspected of having lung cancer who have a central lesion, bronchoscopy is recommended to confirm the diagnosis. However, it is recommended that further testing be performed if bronchoscopy results are non-diagnostic and suspicion of lung cancer remains (Grade 1B; strong recommendation, moderate quality evidence)
- In patients suspected of having lung cancer who have a peripheral lung nodule, and a tissue diagnosis is required due to uncertainty of diagnosis or poor surgical candidacy, radial EBUS is recommended as an adjunct imaging modality (Grade 1C; strong recommendation, low quality evidence)
- 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. (Grade 1C; strong recommendation, low quality evidence)
- In patients suspected of having lung cancer who have a peripheral lesion, and who require tissue diagnosis before further management can be planned, TTNA is a diagnostic option. However, it is recommended that further testing be performed if TTNA results are non-diagnostic and suspicion of lung cancer remains (Grade 1C; strong recommendation, low quality evidence)

National Comprehensive Cancer Network® (NCCN): The NCCN Guideline Version 4.2014, Non-Small Cell Lung Cancer, in a list of principles of diagnostic evaluation, includes endobronchial ultrasound (EBUS)-guided biopsy and navigational bronchoscopy as diagnostic tools that provide important additional strategies for biopsy. In terms of the first diagnostic study to be performed, the least invasive biopsy with the highest yield is preferred. Navigational bronchoscopy, radial EBUS or transthoracic needle aspiration (TTNA) are recommended for patients with peripheral (outer one-third) nodules, and biopsy by EBUS, navigational bronchoscopy or mediastinoscopy is recommended for patients with suspected nodal disease.

Use Outside the U.S.

The superDimension inReach System was licensed by Health Canada in 2009, and received the CE mark for distribution in the European Union in 2002.

The British Thoracic Society Guideline for Advanced Diagnostic and Therapeutic Flexible Bronchoscopy in Adults (Du Rand et al., 2011) includes the following recommendation in a section addressing emerging applications for flexible bronchoscopy:

- Electromagnetic bronchoscopy may be considered for the biopsy of peripheral lesions or to guide TBNA for sampling mediastinal lymph nodes. (Grade D)

Recommendations are graded A, B, C or D. A grade D recommendation indicates evidence level 3 (non-analytic studies, e.g., case reports, case series) or 4 (expert opinion).

Summary

Electromagnetic navigation bronchoscopy (ENB) is an emerging technology that has been proposed to further increase the diagnostic yield of bronchoscopy, particularly in the diagnosis of peripheral lung lesions. There is insufficient evidence in the published peer-reviewed medical literature to determine the safety and efficacy of this procedure, or to determine the diagnostic accuracy of this method compared to currently available biopsy techniques. There is insufficient evidence to demonstrate that ENB impacts treatment of lung cancer or results in improved rates of survival. In addition, invasive diagnostic or therapeutic treatment may still be indicated if results obtained using this method are non-diagnostic or are positive for cancer. Electromagnetic navigation bronchoscopy would therefore not necessarily obviate the need for subsequent surgical intervention.

Electromagnetic navigation is also being evaluated for the placement of fiducial markers in preparation for treatment with external beam radiation/stereotactic radiosurgery. There is insufficient evidence in the peer

reviewed medical literature to establish the safety and clinical utility of electromagnetic navigation bronchoscopy for any indication.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
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[s])

*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.

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