Healthy Blue

Medical Policy

Subject:	Electromagnetic Navigational Bronchoscopy		
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Description/Scope

This document addresses the use of electromagnetic navigational bronchoscopy (ENB) devices as an aid in accessing peripheral lung lesions and masses, which may be inaccessible by standard bronchoscopy. ENB has also been proposed as a means of placing fiducial markers for surgical and radiological procedures.

Position Statement

Investigational and Not Medically Necessary:

Electromagnetic navigational bronchoscopy is considered **investigational and not medically necessary** for all applications.

Rationale

Lung Biopsy

Ost and colleagues (2016) compared several methods used to obtain samples and diagnose peripheral lung nodules and masses. This retrospective study used data obtained from the American College of Chest Physicians (ACCP) Quality Improvement Registry, Evaluation, and Education (AQuIRE) program, which included 15 centers and 581 individuals. Overall, the bronchoscopy procedures were considered diagnostic (specific diagnosis of either benign or malignancy was made) in 53.7% of the peripheral lesions (312/587). Unadjusted for other factors, the diagnostic yield of bronchoscopy alone (without radial endobronchial ultrasound [r-EBUS] or electromagnetic navigation [EMN]) was 63.7%; 57.0% with r-EBUS only; 38.5% with EMN only; and 47.1% with EMN plus r-EBUS. These lower diagnostic yields remained even after adjusting for size, location, transbronchial needle aspiration use or tobacco use. The authors contrast these results with those higher yield results reported in previous small, retrospective studies, suggesting that EMN does not perform as well outside the research setting. This study also addressed lung cancer sensitivity. The overall sensitivity for lung cancer was 60-74%. The minimum and maximum ranges were lower in those procedures which utilized EMN versus those procedures which did not (54%-69% versus 68%-79% respectively). The authors noted that there is little difference in sensitivity between best case sensitivity scenario with EMN and the worst case scenario without EMN. This may be due to limitations with this study, including the retrospective design with limited ability to use surgical resection as the diagnostic gold standard. This study does not support that EMN is superior to bronchoscopy and highlights the need for further comparator studies.

In 2017, Khandar and colleagues published the interim, 1-month results of the NAVIGATE study, a prospective, single arm, multicenter study of individuals who underwent ENB. Participants included individuals undergoing ENB procedures for lung lesion biopsy (n=964), fiducial marker placement (n=210), pleural dye marking (n=17), and/or lymph node biopsy (n=334). The majority of the lesions were in the peripheral/middle lung thirds (92.7%). The primary endpoint was index ENB-related pneumothorax rated grade ≥ 2, as it is applicable to all ENB procedures. At the 12- and 24-month follow-ups, the diagnostic yield of the index ENB procedure will be calculated as the proportion of individuals with a definitive diagnosis. One month follow-up data was obtained on 93.3% of the first 1000 primary cohort participants. Pneumothorax of grade ≥ 2 related to the ENB procedure was reported in 3.2% (32/1000) of the group. Pneumothorax of any grade was reported in 4.9% (49/1000) of the cases. There were 23 individuals who died by the 1-month follow-up, no deaths were considered to be related to the ENB device. Tissue biopsy was successful in 94.4% (910/1000) in those individuals who were diagnosed with primary lung adenocarcinoma or non-small-cell lung cancer NOS and molecular genetic testing was attempted; there was adequate tissue in 56/70 (80%). The onsite pathology sample assessments reported non-malignancy in 372/910 (40.9%) cases, malignancy in 45.8% (417/910) cases and inconclusive results in an additional 13.3% (121/910). Fiducial markers were placed in 210 individuals with operators reporting accurate placement in 208/210 (99.0%) cases. A total of eight (3.8%) grade ≥ 2 pneumothoraces were reported. The authors noted that a 1-month interim analysis is not a sufficient amount of time to calculate a true negative yield or the diagnostic yield. While the results suggest ENB might be a safe alternative for a certain population, further follow-up is needed to determine impact on long-term survival and "will help to set the benchmark for the ideal ENB patient, and define the procedural techniques contributing to enhanced performance" (Khandhar, 2017).

In 2019, the 1 year results of the NAVIGATE study were reported by Folch and colleagues. The purpose of 12-month follow-up was to determine the true diagnosis (malignant or nonmalignant). The study defined initial negative results as results that were diagnostic of a nonmalignant condition or indeterminate results. At 12 months post-procedure, cases reporting subsequent diagnostic tests confirming a nonmalignant diagnosis or without lesion progression on radiographic follow-up were considered true-negative. Cases categorized as false-negative included those cases in which follow-up diagnostics revealed malignancy, lesion growth was noted on repeat diagnostic testing, death due to lung cancer within 12 months, treatment without a confirmed diagnosis or new diagnoses of cancer in the lung from any site. A total of 1215 individuals underwent an ENB aided procedure. A 12-month follow-up was completed on 80.3% (976/1215) of the participants. In those individuals who underwent lung lesion biopsy (n=1157), tissue was obtained in 94.4% of the cases (n=1092). Malignancy was diagnosed in 44.3% (484/1092) of the cases and was negative in 55.7% (608/1092) of the cases. At 12 months, the diagnostic yield was 72.9%. Sensitivity for malignancy was 68.8% (range: 59.9%-68.8%); the reported negative predictive value (NPV) was 56.3% (range: 46.7%-63.8%). The specificity and positive predictive value (PPV) were reported as 100% and the NPV was calculated at 56%. Further evaluation at 24 months will be performed and a recalculation of the indexes will be performed at that time. While the study evaluates a large population, the accuracy of these diagnostic indicators is limited by the significant loss to follow-up of approximately 20%.

Bhatt and associates (2018) reported on the results of a retrospective study of individuals who underwent tissue sampling of lung nodules via guidance by ENB (n=146) or CT (n=149). The modality used was based on the

anticipated yield which was determined by multiple factors including comorbidities such as regional emphysema, location of nodules and the need for concomitant lymph node staging. The lesions in both groups were predominantly peripherally located (2 or less centimeters (cm) from the pleura). The diagnostic yield and complication rates for each procedure were evaluated and compared. The diagnostic yield reported in the CT group was significantly better than the diagnostic yield in the ENB group (86.0% versus 66.0%; p<0.001 respectively). The rate of major complications, defined as symptomatic hemorrhage or pneumothorax requiring chest tube or hospital admission were not significantly different between the CT and ENB groups. In addition, the authors noted that the intra-procedural time was lower in the CT guided group compared to the ENB group. The authors concluded that CT transthoracic biopsy could be considered the preferred approach when feasible.

A number of meta-analyses have been published comparing methods of sampling peripheral pulmonary lesions. A 2014 systematic review and meta-analysis by Gex and colleagues included a total of 15 trials with 1033 lung nodules in 971 individuals. Successful navigation to the peripheral lung nodule was achieved 97.4% of the time, with a definitive diagnosis reported in 64.9% of the cases. The overall diagnostic accuracy was 73.9% and the sensitivity for lung cancer was 71.1%. However, the negative predictive value for cancer was only 52.1% and the overall negative predictive value was suboptimal at 78.5%. The authors noted several limitations related to this review. The methodological quality of the studies, as evaluated by the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) scores, was poor. None of the studies compared ENB to the gold standard, surgical resection. In addition, there were inconsistencies in the reported outcomes between studies such as the definition of diagnostic yield, which in several studies includes more favorable outcomes such as diagnostic or malignancy status accuracy. The authors noted that ENB's performance, compared to CT-guided transthoracic needle biopsies, seems slightly inferior and further adequately powered prospective studies are needed.

In a 2015 meta-analysis, Zhang and colleagues evaluated the overall diagnostic yield and accuracy of ENB-based targeted biopsies in detecting peripheral lesions. This meta-analysis included 17 studies with a total of 1106 individuals with peripheral lung lesions. In the 15 studies which reported true positive (TP) and true negative (TN) data, the sensitivity ranged from 50%-100% with a pooled sensitivity of 82% (95% confidence interval [CI], 78-85%). The pooled specificity of this population was reported at 100%. The positive likelihood ratio (PLR), negative likelihood ratio (NLR), and diagnostic odds ratio (DOR) were reported as 18.67 (95% CI, 9.04-38.55), 0.22 (95% CI, 0.15-0.32) and 97.36 (95% CI, 43.75-216.69) respectively. There were several limitations associated with this meta-analysis. There was significant statistical heterogeneity found with the sensitivity and NLR outcomes. The authors of the study noted that the methodological quality of the studies was poor. None of the studies included a comparison to the current gold standard procedure of surgery. In addition, selection bias may have been a factor as it was not clear whether the participants were representative of the population which would be suitable ENB-candidates in the clinical setting.

McGuire and associates (2020) determined the comparative diagnostic accuracy, sensitivity, and negative predictive value for R-EBUS and ENB in sampling PPLs (peripheral pulmonary lesions). A total of 17 ENB and 24 R-EBUS studies were included with 2097 participants in the R-EBUS group and 1107 participants in the ENB group. While the authors concluded that both technologies have a high proportion of successful localization (90.2%

versus 98.2%, respectively) with similar diagnostic accuracy for malignancy (72.4% versus 76.4%, respectively), the analysis is limited by a high amount of between-study heterogeneity and the overall poor methodological quality of the studies. The authors noted:

> Given the equipoise with respect to the overall diagnostic superiority of R-EBUS versus ENB, future prospective study in the form of a randomized trial comparing test performance of each technology for a sampling of PPLs compared with a well-defined reference standard is warranted.

The 2013 American College of Chest Physicians Evidence Based Guidelines includes a recommendation for electromagnetic navigation guidance:

> 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).

This recommendation is based on low quality evidence; higher quality evidence may impact confidence in this recommendation and may even change the estimate itself. Ost and colleagues (2016) noted that much of the data was obtained at centers of excellence with a carefully selected study population; it is uncertain how representative this study population is of the general population.

Fiducial Marker Placement or Pleural Dye Marking of Lung Nodule

Fiducial markers (FM) are used as a means of motion management during gated stereotactic body radiation therapy (SBRT) for the treatment of non-small cell lung cancer. FMs can also be used as a visualization aid during surgery with or without pleural dye marking. FMs allow the operator to confirm correct positioning on the target center and to facilitate accuracy of high-dose radiation treatments to small targets and targets in close proximity organs. FMs are placed percutaneously with image guidance or through video bronchoscope. ENB has been proposed as an alternative method of FM placement that may result in fewer complications (Bowling, 2019).

Bowling and associates (2019) reviewed the safety and accuracy outcomes of ENB-guided FM placement in the participants of the NAVIGATE trial who underwent FM placement with the superDimension™ navigation system. The NAVIGATE trial, a prospective, multicenter, observational cohort study of ENB using the superDimension™ navigation system, included 258 adults who underwent elective FM placement. Concurrent procedures included FM placement and lung biopsy, FM placement and dye marking, FM placement alone and FM placement and dye marking and biopsy. The median overall procedure time was 57 minutes and 31 minutes for the ENB procedure; general anesthesia was used in 68.2% (176/258) of the cases. An average of 2.2 ± 1.7 FMs were placed in each session. A placement accuracy of 99.2% was based on subjective operator assessment, which authors admit may not be the most clinically appropriate indicator for SBRT success. When confirmed during follow-up imaging, 94.1% of the markers remained in place. Complication rates were reported as procedure-related pneumothorax rate 5.4% (14/258) overall, grade 2 or higher pneumothorax rate 3.1% (8/258) and respiratory failure rate 1.6% (4/258).

Similar to the studies regarding ENB for biopsy, this study lacks a comparator group using an established means of FM placement.

Using data from the NAVIGATE trial, Bowling and colleagues (2019a) reported on the 1 month interim analysis of 23 individuals who underwent pleural dye marking prior to lung resection. The objective of the study was to evaluate usage patterns, techniques and performance. Dye marking was conducted alone or concurrently with lesion or lymph node biopsy and/or FM placement. Fluoroscopy was used in all cases, EBUS was used in 4/23 cases. Following dye marking, surgical resection was attempted in all cases and the surgeon considered pleural dye marking adequate in 21/23 cases (91.3%). The authors note, "The combined method of ENB, fluoroscopy and radial EBUS may be advantageous when indicated and available." It is unclear what additional benefit ENB provides during pleural dye marking.

Yanagiya and associates (2020) performed a meta-analysis evaluating the safety and efficacy of preoperative bronchoscopic marking. The authors used pooled data from several methods as well as subgroup analyses on individual methods. The most common method evaluated, dye marking under ENB, was used in 15 of the 25 total studies included in the review. The subgroup analyses calculated in a successful marking rate for ENB of 0.94 (95% CI, 0.91-0.96), but reported significant heterogeneity. The successful resection rate for ENB was 0.99 (95% CI, 0.97-1.00). These results were similar to the pooled rates (0.97; 95% CI, 0.95-0.99 and 0.98; 95% CI, 0.96-1.00, respectively). While bronchoscopic marking in general and ENB in particular appeared to be effective and safe, the majority of studies in the meta-analysis were single armed retrospective observational studies with a limited number of participants. In addition, this analysis did not consider elements which could affect outcomes including characteristics of the nodules or the surgical procedure used.

Summary

There have been a number of prospective and retrospective studies evaluating the outcomes of ENB-guided lesion biopsy, (Bhatt, 2018; Bolton, 2014; Bolton, 2018; Gildea, 2006; Krimsky, 2013; Loo, 2014; Nabavizadeh, 2014; Odronic, 2014; Oh, 2021; Ozgul, 2016; Schwarz, 2006; Wilson, 2007). While the NAVIGATE study attempts to provide a real world, practical design, the results of the study are limited by the absence of a protocolized approach (Thiboutot, 2019). There remains a lack of studies that include head-to-head comparisons of ENB with established biopsy techniques; the impact on care management and clinical outcomes is also unclear at the present time. In addition, there is a paucity of literature to support the use of ENB to place surgical or radiological markers (Bolton, 2015; Bolton, 2017; Nabavizadeh, 2014; Schroeder, 2010).

Background/Overview

In 2021, lung cancer will be diagnosed in approximately 235,760 individuals in the United States and will cause an estimated 131,880 deaths (ACS, 2021). Lung cancer screening using low-dose CT of the chest is recommended in individuals considered at high risk (NCCN, 2021). Over 25% of the computed tomography (CT) scans in the high-risk population will be abnormal. These screening CT chest scans can result in a high proportion of false-positive

peripheral pulmonary lesions, up to 96.4% (McGuire, 2020). While early detection is integral to improved outcomes, false positive results can result in over-diagnosis and increased testing, including invasive testing. Invasive testing increases the risk of complications such as pneumothorax.

Individuals with suspect nodules can undergo biopsy using several techniques, depending upon nodule location. Central masses may typically be biopsied by bronchoscopy or mediastinoscopy. Peripheral nodules may benefit from radial EBUS, endoscopic ultrasound or transthoracic needle aspiration (TTNA) (NCCN, V5.2021). ENB has also been proposed as an emerging technology aimed primarily at improving the diagnostic yield of transbronchial tools used during bronchoscopy procedures to sample peripheral parenchymal lung lesions not visible through the bronchoscope. Preliminary studies have suggested that this diagnostic tool may achieve similar diagnostic yields to transthoracic biopsy of peripheral lesions with potential for less risk of pneumothorax. In addition to comparison with transthoracic biopsy, ENB is also compared to endoscopic ultrasound (EUS), another technique used during bronchoscopy for biopsy of peripheral lung lesions. It is important to note that ENB is not a real-time procedure. A CT scan is performed on one day, with a single-breath hold and the individual not moving, and on another day (or potentially later the same day) in another setting, the bronchoscopy is performed while the individual is awake and breathing with a bronchoscope placed in the airway, (which typically produces coughing and gagging to some extent). The importance of this difference is that the lesions detected on the single breath hold CT scan will not necessarily be in the same physical location as in a breathing individual during a bronchoscopy. In a retrospective review, Chen and colleagues (2015) evaluated the records of 46 individuals with pulmonary lesions who had two pre-procedure CT scans performed prior to bronchoscopy, one CT scan at full inspiration and a second CT scan at end-exhalation during tidal volume breathing. The average motion of all 85 pulmonary lesions identified was 17.6 mm with lower lobe nodules showing significantly more movement than upper lobe nodules. The authors noted that the movement on planning chest CT scans could potentially significantly affect the diagnostic yield during ENB procedures.

Devices

The ENB devices are used in conjunction with standard bronchoscopy and are not FDA approved as stand-alone surgical devices/procedures. ENB is used to guide the bronchoscope and bronchial tool to an intended target located in or adjacent to the bronchial tree on a path indicated by CT scan, and visualizes the target and the interior of the tree. The ENB devices include sensors placed on the chest to provide real time navigation during the procedure.

The U.S. Food and Drug Administration (FDA) has approved two devices. The SuperDimension™ Navigation System (Medtronic, Minneapolis, MN) received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in 2008. The system is intended to display images of the tracheobronchial tree, aiding the physician in guiding endoscopic tools or catheters in the pulmonary tract for diagnostic purposes or to enable marker placement within soft lung tissue. The second device, SpiN Drive® System (Olympus Corporation of the America, Center Valley, PA), is also known as the ig4™ EndoBronchial System which received FDA clearance in December 2009.

The superDimension/Bronchus inReach System further describes the device. Overall, the description applies to both the superDimension/Bronchus inReach System and the SpiN Drive System devices:

> …The system is used as an adjunct to standard bronchoscopy. It provides a three-dimensional roadmap of the lungs generated from standard CT images taken of the lung prior to the procedure. Once the physician creates the plan and maps the individual's lungs, the inReach System's disposable guide catheter is used with standard bronchoscopic tools to reach the targeted lesion. The catheter's tip contains an electromagnetic location sensor that allows its location to be overlaid in real time on the pre-generated CT roadmap of the lungs. The physician can steer the catheter 360 degrees to reach distant locations in the bronchial tree.
>
> Pre-procedure computed tomography (CT) is converted to 3-dimensional (3-D) and "virtual" bronchoscopy formats. Landmarks, including the target lesion(s), are identified on the images. Bronchoscopy is then performed with the individual lying on an electromagnetic board; actual landmarks are compared to the image landmarks, and a steerable probe with a sensor at the tip, whose location is monitored by the electromagnetic field linked to the 3-D CT images, is navigated to the target lesion.

In an attempt to address the lack of real-time imaging, a limitation associated with ENB, digital tomosynthesis using conventional C-arm, or fluoroscopic ENB (F-ENB), was introduced as part of a software upgrade of the superDimension package. The ILLUMINSITE™ platform has been proposed as a means to mitigate CT body divergence, which is the difference between the location of the nodule on the pre-procedure CT scan and the location during the procedure. In addition to the total IV anesthesia associated with ENB, F-ENB requires neuromuscular blockade in order to capture the tomosynthesis images. Currently, the evidence regarding this new technology is limited to a small retrospective study (Aboudara, 2020).

Definitions

Bronchoscopy: An endoscopic test that utilizes either a rigid or flexible scope, in order to visualize and collect samples (washing, brushing, biopsy, culture, etc.) from the endobronchial tubes/branches of the respiratory system.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT

31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation [add-on code]

ICD-10 Diagnosis

All diagnoses

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    - Lung Cancer (Non-Small Cell). Available at: http://www.cancer.org/acs/groups/cid/documents/webcontent/003115-pdf.pdf. Accessed on June 30, 2021.
    - Key Statistics for Lung Cancer. Available at: https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html. Accessed on June 30, 2021.
2. American Lung Association. Lung Cancer Diagnosis. Available at: http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/lung-cancer/diagnosing-and-treating/how-lung-cancer-diagnosed.html. Accessed on June 30, 2021.
3. National Heart, Lung and Blood Institute. What is Bronchoscopy? Available at: https://www.nhlbi.nih.gov/health-topics/bronchoscopy. Accessed on June 30, 2021.

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Electromagnetic Navigational Bronchoscopy (ENB)
ig4 EndoBronchial System
iLogic Electromagnetic Navigation Bronchoscopy
ILLUMISITE™
LungPoint® Virtual Bronchoscopic Navigation
SpiN Drive System
superDimension/Bronchus inReach System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/12/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Rationale, Background/Overview, References, and Websites sections.
Reviewed	08/13/2020	MPTAC review. Updated Rationale, Background/Overview, References, and Websites sections.
Reviewed	08/22/2019	MPTAC review. Updated References and Websites sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Websites, and References sections.
Reviewed	11/03/2016	MPTAC review. Updated Rationale, Websites, and References sections.
Reviewed	11/05/2015	MPTAC review. Updated Description, Rationale, Websites for Additional Information, and References sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Rationale, and Reference sections.
Reviewed	11/14/2013	MPTAC review. Updated Rationale and References sections.
Reviewed	11/08/2012	MPTAC review. Updated References section.
Reviewed	11/17/2011	MPTAC review. Updated References section.
Revised	11/18/2010	MPTAC review. The brand name was removed from the position statement. Updated Rationale and References section.
Reviewed	11/19/2009	MPTAC review. Updated References section. Updated Coding section with 01/01/2010 CPT changes.
New	11/20/2008	MPTAC review. Initial document development.