Anthem

Clinical UM Guideline

Subject: Navigational Bronchoscopy
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Description

This document addresses the use of navigational bronchoscopy (NB) devices as an aid in accessing peripheral lung lesions and masses, which may be inaccessible by standard bronchoscopy. This document includes the following techniques:

- Electromagnetic navigational bronchoscopy (ENB)
- Artificial Intelligence (AI) Tomography with Augmented Fluoroscopic Guidance
- Robotic assisted bronchoscopy

Navigational bronchoscopy has also been used as a means of placing fiducial markers for surgical and radiological procedures.

Clinical Indications

Medically Necessary:

Navigational bronchoscopy is considered **medically necessary** for the following indications (A or B):

A. In individuals for whom nonsurgical biopsy is indicated when both transthoracic needle biopsy and conventional bronchoscopy are considered inadequate to accomplish the diagnostic or interventional objective; **or**
B. For the pre-treatment placement of fiducial markers within lung tumor(s).

Not Medically Necessary:

Navigational bronchoscopy is considered **not medically necessary** for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline 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 may be Medically Necessary when criteria are met:

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

When services are Not Medically Necessary:
For the procedure code listed above when criteria are not met and for all other indications.

Discussion/General Information

In 2023, lung cancer will be diagnosed in approximately 238,340individuals in the United States and will cause an estimated 127,070deaths (ACS, 2023). Lung cancer screening using low-dose CT of the chest is recommended in individuals considered at high risk (National Comprehensive Cancer Network [NCCN], V1.2024). 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. Nodules which are located in the periphery of the lungs account for more than 70% of potential malignant lesions (Stone, 2022). Peripheral nodules may benefit from navigational bronchoscopy, radial endobronchial ultrasound (EBUS), or transthoracic needle aspiration (TTNA) (NCCN, V3.2023).

Contraindications to bronchoscopy or TTNA

Surgical biopsy is recommended in individuals with resectable nodules who are a low to intermediate surgical risk when there is a high clinical suspicion for cancer. This approach potentially avoids the need for separate diagnostic and therapeutic procedures and minimizes the time to treatment. However, the population with suspicious nodules are frequently older with underlying respiratory disorders, and more likely to be high risk surgical candidates (Seijo, 2016). Established biopsy techniques such as bronchoscopy and TTNA are used when the surgical approach is not appropriate. These techniques are not adequate in all instances and navigational bronchoscopy may be a more appropriate choice when conventional bronchoscopy or TTNA would not be an adequate diagnostic technique.

The utility of conventional bronchoscopy is dependent on the size and location of the nodules. In small peripheral lesions, conventional bronchoscopy is associated with poor diagnostic yields (Seijo, 2016). The American College of Chest Physicians (ACCP) guidelines (2013) do not recommend conventional bronchoscopy for small pulmonary nodules unless a bronchus sign is present. With increased screening and improved imaging available, smaller nodules are being identified. The overall sensitively of

conventional bronchoscopy decreases as the size of the nodules decrease (Seijo, 2016).

TTNA has been shown to have a high sensitivity, but there is an elevated risk of adverse events such as pneumothorax or pulmonary hemorrhage (Chockalingam, 2015; Hong, 2021). The risks associated with TTNA increase in older individuals, individuals with a significant past medical history, larger lesions or who may be uncooperative during the procedure. The majority of TTNA relative contraindications are related to respiratory comorbidities such as pulmonary hypertension, emphysematous disease and chronic obstructive pulmonary disease (COPD). Large bullae can result in a post-procedure pneumothorax (Chockalingam, 2015). Nodule size and location are factors which affect the risks associated with TTNA. In nodules less than 20mm, the risk of complications is 11 greater than larger nodules. The complication risk increases as the distance from the nodule to the pleural surface increases (Seijo, 2016).

The 2013 ACCP Evidence Based Guidelines recommend bronchoscopy for individuals with central lesions. Peripheral pulmonary lesions (PPLs), which can be defined as “lesions surrounded by lesions surrounded by normal pulmonary parenchyma without any computed tomography evidence of endobronchial abnormalities” are typically not visible on bronchoscopy (Jiang, 2020). For individuals with peripheral lung lesions which are difficult to reach with conventional bronchoscopy, the ACCP recommends electromagnetic navigation guidance if available and TTNA is ENB is not available. The British Thoracic society guideline on the management of pulmonary nodules (Callister, 2015) notes the following evidence statement:

> Diagnostic yield of bronchoscopy may be increased by the use of fluoroscopy, electromagnetic navigation and radial endobronchial ultrasound and in the presence of a CT bronchus sign. However, yield remains relatively low for lesions <2 cm in the peripheral third of the lung.
>
> > Grade D: Evidence level 3 or 4 or Extrapolated evidence from studies rated as 2+
> > Evidence level 3: Non-analytical studies—for example, case reports, case series

In a retrospective cohort analysis, Vachani and colleagues (2022) reported on population-based estimates regarding complications and risk factors associated with transthoracic needle biopsy (TTNB). Individuals who underwent a stand-alone TTNB in 2017 or 2018 (n=16971) were included. Procedure related complications (pneumothorax, hemorrhage, and air embolism) were analyzed to estimate the association of these complications with setting of care and individual demographic and clinical characteristics. Within 3 days post-procedure, 25.8% experienced a complication (pneumothorax 23.3%, hemorrhage 3.6%, and air embolism 0.02%). Inpatient status and a history of COPD, a previous lung cancer screening or bronchoscopy or oral anticoagulants or antiplatelet therapy were associated with an increased risk of pneumothorax or hemorrhage.

In summary, transthoracic needle biopsy and conventional bronchoscopy may be considered inadequate to accomplish their intended diagnostic or interventional objective in certain individuals based on a number of considerations. These considerations include the anatomic location of the nodule/lesion or individual risk status. ENB may be more appropriate for lesions that are located in the lung periphery and in individuals who are at high risk for complications associated with transthoracic needle biopsy and/or conventional bronchoscopy (for example, in individuals who are at high risk of pneumothorax, or when lesions have surrounding emphysema).

Lung Biopsy

ENB

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.

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. The NAVIGATE study was developed in order to address concerns about the clinical utility of ENB outside of the research setting. 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 a direct result of the ENB procedure. 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 pneumothoraxes were reported.

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%.

Folch and associates (2022) reported on the 24-month results of NAVIGATE participants. The majority of the individuals underwent ENB for lung lesion biopsy (n=1329 or 95.7%). A total of 1260/1329 (94.8%) of individuals completed the ENB procedure and tissue

was obtained. A result positive for malignancy was obtained in 537/1260 (42.6%) of the time and in 57.4% (723/1260) of cases a negative result was obtained. At 24 months, the global diagnostic yield was 67.8% the sensitivity analysis ranged from 61.9% to 70.7%, based upon the 117 samples which remained indeterminate. ENB was associated with a low complication risk, with a reported 3.2% rate of pneumothorax which required intervention or hospitalization. The authors summarize that although other studies have reported higher diagnostic yields, the NAVIGATE study is designed as a pragmatic study to evaluate outcomes in the real world.

McGuire and associates (2020) determined the comparative diagnostic accuracy, sensitivity, and negative predictive value for radial-EBUS (R-EBUS) and ENB in sampling peripheral pulmonary lesions (PPLs). 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. Both technologies report a high proportion of successful localization (90.2% versus 98.2%, respectively) with similar diagnostic accuracy for malignancy (72.4% versus 76.4%, respectively).

In 2022, Zheng and colleagues reported the results of a prospective, multicenter, randomized controlled trial to compare the diagnostic value of EBUS used with an ENB system versus EBUS alone. Data from a total of 385 individuals with peripheral pulmonary nodules (PPN) suspected to be malignant were analyzed, 193 in the ENB-EBUS group and 192 in the EBUS group. The diagnostic yields were 82.9% (95% confidence interval [CI], 77.6–88.2%) in the ENB-EBUS group and 73.4% (95% CI, 67.2–79.7%) in the EBUS group, a difference that was statistically significant. The authors concluded that combining ENB with EBUS improved the ability to locate PPN and the diagnostic yield compared to EBUS alone.

ENB with real-time imaging

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 used 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. The use of adjunctive real-time imaging with ENB can improve the process of obtaining diagnostic tissue from lung nodules by overcoming the limitations of CT scan to body divergence (Aboudara, 2020; Avasarala, 2022; Podder, 2022; Pritchett, 2018).

Artificial Intelligence (AI) Tomography with Augmented Fluoroscopic Guidance

In 2018, the LungVision™ System (Body Vision Medical Inc., New York, NY) received FDA clearance as a tool, used with standard bronchoscopic instruments, to guide the instruments to the target area within the respiratory system. The approval is based upon a predicate guide sheath. The LungVision system provides guidance during a bronchoscopy via multi-modal image fusion of preoperative CT and interoperative fluoroscopy. This allows real-time augmented endobronchial fluoroscopic navigation and guidance. The initial LungVision device included multi-image fusion capabilities. LungVision's second generation system incorporated AI algorithms, C-arm based tomography (CABT) technology and navigation tool integration into the system (Pertzov, 2021). Studies support results comparable to other forms of navigational bronchoscopy (Cicenia, 2021; Pertzov, 2018).

Robotic assisted bronchoscopy

The Monarch® Platform (Auris Health Inc., Redwood City, CA) received FDA clearance on March 22, 2018. The system includes 2 robotic arms and the electronic systems used to operate the arms. Navigational support is provided by ENB using a CT scan obtained within 2 weeks pre-procedure. A flexible bronchoscopy is first performed to confirm the absence of endobronchial disease and provide topical anesthesia. The scope is then advanced using direct visualization, ENB and fluoroscopic guidance. Once the targeted location is reached, an R-EBUS probe is inserted into the working channel to view the area. Following R-EBUS visualization, TBNA is used to obtain samples from the targeted lesions (Chen, 2020).

The Ion™ Endoluminal System (Intuitive Surgical, Inc, Sunnyvale, CA) received clearance by the FDA in February 2019. The Ion System uses a CT scan and proprietary software to generate a 3D visualization of the airway to identify the nodule and map and save a pathway to the targeted nodule, which is loaded into the controller. This preloaded pathway and real-time vision using a fiberoptic shape sensor is used to provide location information while accessing the nodule. The catheter is locked in place once the nodule is accessed and a needle is advanced through the catheter to obtain the sample.

The BENEFIT study, a prospective, multicenter pilot and feasibility study evaluated the use of a robotic bronchoscopic system in accessing and obtaining peripheral pulmonary lesions (Chen, 2020). Individuals with peripheral pulmonary lesions 1 to 5 cm in size with no evidence of mediastinal or hilar lymph node disease were included (n=54). The primary efficacy point was confirmation of lesion localization with R-EBUS. Lesion localization with R-EBUS was confirmed in 96.2 % (51/53) of the cases. The diagnostic yield at 12-month follow-up was reported as 74.1% (40/54). Pneumothorax was reported in 3.7% (2/54) of the cases, 1 of which required tube thoracostomy.

Fiducial Marker (FM) Placement or Pleural Dye Marking of Lung Nodule

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. Accurate placement of FMs or pleural dye marking is confirmed by follow-up imaging or during surgical resection (Folch, 2022). ENB may be used 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).

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%).

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). Bronchoscopic marking in general and ENB in particular appeared to be effective and safe.

Summary

One of the benefits of navigational bronchoscopy is the ability to biopsy and place fiducial markers or dye markers in the same procedure (Folch, 2022). Navigational bronchoscopy also allows for the biopsy of multiple nodules and mediastinal staging within the same procedure (Folch, 2022). While the lack of real-time image guidance and the presence of CT-to-body divergence does limit the diagnostic yields compared to other techniques, such as TTNA, navigational bronchoscopy does provide an alternative method of obtaining samples in individuals when other options are not available (Folch, 2022). In individuals for whom nonsurgical biopsy is indicated when both transthoracic needle biopsy and conventional bronchoscopy are considered inadequate to accomplish the diagnostic or interventional objective, use of the device is likely to provide additional diagnostic information. In an attempt to address the shortcomings of navigational bronchoscopy and augment clinical utility, versions of navigational bronchoscopy combined with other technologies have been developed. ENB continues to be the most common form of navigational bronchoscopy utilized.

Definitions

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

Diagnostic yield: A subset of the overall yield of tissue obtained during bronchoscopy which results a positive or negative diagnosis.

Navigational systems: Systems include a pre-operative imaging/planning component, which maps the intended course to the lesion. During the bronchoscopy, sensors attached to the bronchoscope allow for tracking of the catheter along the intended pathway. Use of navigational systems are intended to be used to access peripheral lung nodules and improve diagnostic yield.

Robotic bronchoscopy: A navigational bronchoscopy platform which includes a robotic arm, allowing the physician to interact with the bronchoscope through a controller arm. This direct interaction is thought to allow for more precise control by the operator.

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Index

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.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, References and Websites for Additional Information sections.
New	11/10/2022	MPTAC review. Initial document development. Moved content of MED.00099 Navigational Bronchoscopy to clinical utilization management guideline document with the same title. Added medically necessary criteria for navigational bronchoscopy. Revised investigational and not medically necessary to not medically necessary when criteria are not met.

the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.