Corporate Medical Policy

Electromagnetic Navigation Bronchoscopy

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Origination:	1/2010
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Description of Procedure or Service

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a three-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs so that suspicious lesions can undergo biopsy and to allow for placement of fiducial markers.

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography (CT) scans. Although most of these nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when cancer is diagnosed later in the disease course. The method used to diagnosis lung cancer depends on a number of factors, including lesion size and location, as well as the clinical history and status of the patient. There is generally greater diagnostic success with centrally located and larger lesions.

Peripheral lung lesions and solitary pulmonary nodules (SPN) (most often defined as asymptomatic nodules less than 30 mm) are more difficult to evaluate than larger, centrally located lesions. There are several options for diagnosing them; none of the methods are ideal for safely and accurately diagnosing malignant disease. Sputum cytology is the least invasive approach. Reported sensitivity rates are relatively low and vary widely across studies; sensitivity is lower for peripheral lesions. Sputum cytology, however, has a high specificity and a positive test may obviate the need for more invasive testing. Flexible bronchoscopy, a minimally invasive procedure, is an established approach to evaluating pulmonary nodules. The sensitivity of flexible bronchoscopy for diagnosing bronchogenic carcinoma has been estimated at 88% for central lesions and 78% for peripheral lesions. For small peripheral lesions, less than 1.5 cm in diameter, the sensitivity may be as low as 10%. The diagnostic accuracy of transthoracic needle aspiration for solitary pulmonary nodules tends to be higher than that of bronchoscopy. The sensitivity and specificity are both approximately 94%. A disadvantage of transthoracic needle aspiration is that a pneumothorax develops in 11%–25% of patients, and 5%–14% require insertion of a chest tube. Positron emission tomography (PET) scans are also highly sensitive for evaluating pulmonary nodules, yet may miss small lesions less than 1 cm in size. Surgical lung biopsy is the gold standard for diagnosing pulmonary nodules, but is an invasive procedure.

Recent advances in technology may increase the yield of established diagnostic methods. CT scanning equipment can be used to guide bronchoscopy and bronchoscopic transbronchial needle biopsy, but have the disadvantage of exposing the patient and staff to radiation. Endobronchial ultrasound (EBUS) by radial probes, previously used in the perioperative staging of lung cancer, can also be used to locate and guide sampling of peripheral lesions. EBUS is reported to increase the diagnostic yield of flexible bronchoscopy to at least 82%, regardless of the size and location of the lesion.

Another proposed enhancement to standard bronchoscopy is electromagnetic navigation bronchoscopy (ENB) using the InReach™ system. This technology uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. The three phases of the procedure using the InReach system are as follows:

1. Planning phase: The previously taken CT scans are loaded onto a computer, and proprietary software is used to construct a three-dimensional image of the patient's lungs, with anatomical landmarks identified. The file containing this information is transferred to a computer for use during the procedure;

2. Registration phase: A steerable navigation catheter is placed through the working channel of a standard bronchoscope. The anatomical landmarks identified in the planning phase are viewed on the three-dimensional image from phase 1, and these virtual images are correlated with the actual image from the video bronchoscope.

3. Navigation phase: The steerable navigation catheter is moved toward the target, and the real-time location of the catheter's tip is displayed on the CT images. When the navigation catheter reaches the target, it is locked in place. Once this occurs, endoscopic tools can be inserted through the channel in the catheter to the target. This includes insertion of a transbronchial forceps to biopsy the lesion. In addition, the guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guide wire inserted through the catheter.

Regulatory Status

In September 2004, the superDimension/Bronchus (superDimension Ltd, Herzliya, Israel) InReach system was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The system includes planning and navigation software, a disposable extended working channel and a disposable steerable guide. The FDA cleared indication is for displaying images of the tracheobronchial tree that aids physicians in guiding endoscopic tools in the pulmonary tract. The device is not intended as an endoscopic tool; it does not make a diagnosis; and it is not approved for pediatric use. As of June 2016, the current version of the product is the Medtronic SuperDimension Navigation System (Medtronic, Minneapolics, MN).

In December 2009, the ig4 EndoBronchial system (Veran Medical; St. Louis, MO) was cleared for marketing by the FDA through the 510(k) process. The system was considered to be substantially equivalent to the InReach system and is marketed as the SPiN™ Thoracic Navigation System.

In April 2018, LungVision (Body Vision Medical) was cleared for marketing by the FDA through the 510(k) process (K172955).). The FDA determined that this device was substantially equivalent to existing devices for use "segment previously acquired 3D CT [computed tomography] datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedure".

Several additional navigation software-only systems have been cleared for marketing by the FDA through the 510(k) process. These include:
- December 2008: The LungPoint virtual bronchoscopic navigation (VPN) system (Broncus Technologies, Mountain View, CA).
- June 2010: The bf-NAVI virtual bronchoscopic navigation (VPN) system (Emergo Group, Austin, TX)
- March 26, 2018: Auris Health Inc., Monarch Platform (Redwood City, California).
- February 2019: Intuitive Surgical, Inc. Ion™ endoluminal system (Sunnyvale, California).

Two ENB systems are currently available, the SPiN Thoracic Navigation System™ (Veran Medical Technologies) and the superDimension™ navigation system (Medtronic).

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Electromagnetic Navigation Bronchoscopy when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy

When Electromagnetic Navigation Bronchoscopy is covered

Electromagnetic Navigation Bronchoscopy is considered medically necessary for one of the following indications:

- Patients with a suspicious pulmonary nodule that is deemed inaccessible by standard methods (e.g. peripheral nodule) or when standard methods have failed; **OR**
- Patients with a highly suspicious solitary pulmonary nodule who pose an unacceptable risk (e.g., bullous lung disease, diffuse emphysema) for a more invasive diagnostic procedure; **OR**
- Patients with an identified lung lesion(s) and a diagnosis of co-existing cancer in whom further determination of the lung lesion will impact staging of the primary tumor and thus impact the treatment plan; **OR**
- Placement of fiducial markers in patients who are not candidates for surgical intervention and who have elected to undergo radiation therapy.

When Electromagnetic Navigation Bronchoscopy is not covered

Use of electromagnetic navigation bronchoscopy for any other indication is considered **investigational**.

Policy Guidelines

For individuals who have suspicious peripheral pulmonary lesion(s) when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to sample the pulmonary lesion(s), the evidence includes meta-analyses, a randomized controlled trial, and uncontrolled observational studies. A 2020 meta-analysis of 40 studies and a 2015 meta-analysis of 17 studies of ENB reported a large pooled positive likelihood ratio but a small negative likelihood ratio. Similarly, a 2014 meta-analysis of 15 studies found that navigation success was high, but diagnostic yield and negative predictive value were relatively low. Both systematic reviews assessed the methodological quality of the evidence as low. Results from two large prospective multicenter uncontrolled studies, AQuiRE and NAVIGATE, provide information about test characteristics and safety of ENB. An analysis of more than 500 patients included in the AQuiRE registry found a diagnostic yield of ENB that was lower than in other studies, and lower than bronchoscopy without ENB or endobronchial ultrasound (EBUS). In the US cohort of the NAVIGATE study, the 12-month diagnostic yield was 72.9%. Overall, 4.3% of patients experienced pneumothorax, and pneumothorax requiring hospitalization or intervention occurred in 35 of 1215 patients (2.9%). Bronchopulmonary hemorrhage overall occurred in 2.5% of patients overall

and Common Terminology Criteria for Adverse Events grade 2 or higher in 1.5%. There were no deaths related to the ENB device. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. ENB is generally reserved for the most difficult patients, who are poor or borderline candidates for surgery and transthoracic sampling. In this context, the "low yield" observed in observational studies was actually high for this highly selected population. ENB, when used as an option in the armamentarium of the bronchoscopist, is a highly useful and low-risk modality for proper diagnosis and staging of lung cancer. For example, patients who are able to achieve a positive biopsy result through ENB benefit by getting a diagnostic result to appropriately guide treatment while avoiding transthoracic needle biopsy which has a 2-4 times higher risk of pneumothorax than a bronchoscopic biopsy approach. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to place the markers near the pulmonary lesion(s), the evidence includes one comparative observational study and several case series. The relevant outcomes are health status measures and treatment-related morbidity. In the largest series, a subgroup analysis of 258 patients from the NAVIGATE study, the subjective assessment of outcome was that 99.2% of markers were accurately placed and 94.1% were retained at follow-up. Pneumothorax of any grade occurred in 5.4% of patients, and grade 2 or higher pneumothorax occurred in 3.1%. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. The key advantage of ENB placement is the markedly reduced risk of pneumothorax compared to the transthoracic approach. Patients being treated with targeted radiation are typically those with advanced respiratory disease who cannot undergo surgical resection. They are also more at risk for pneumothorax and resultant further complications. As the markers need to be near and not necessarily in a lesion, the accuracy advantage of a transthoracic approach is outweighed by the safety advantage of ENB over a transthoracic approach. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

While the evidence base consists largely of case series, there is some evidence that ENB provides a minimally invasive option for a select subset of patients where a tissue diagnosis is not feasible by conventional bronchoscopy methods. Diagnostic rates appear comparable to transthoracic needle biopsy for these patients.

The V.5.2020 National Comprehensive Cancer Network (NCCN) clinical practice guideline on non-small-cell lung cancer states that the strategy for diagnosing lung cancer should be individualized, and the least invasive biopsy with the highest diagnostic yield is preferred as the initial diagnostic study.

I. For patients with central masses and suspected endobronchial involvement, bronchoscopy is preferred.
II. For patients with peripheral (outer one-third) nodules, either navigation bronchoscopy, radial EBUS [endobronchial ultrasound] or TTNA [transthoracic needle aspiration] is preferred.
III. For patients with suspected nodal disease, EBUS, EUS, navigation biopsy or mediastinoscopy is preferred.

In 2013, the American College of Chest Physicians issued updated guidelines on the diagnosis of lung cancer. Regarding ENB, the guideline stated: “In patients with peripheral lung lesions difficult to reach with conventional bronchoscopy, electromagnetic navigation guidance is recommended if the equipment and the expertise are available.” The authors noted that the procedure can be performed with or without fluoroscopic guidance and has been found to complement radial probe ultrasound. The strength of evidence for this recommendation as grade 1C, defined as “Strong recommendation, low- or very-low-quality evidence.”

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *31627*

Code 31627 is an add-on code that is used in conjunction with CPT codes 31615, 31622-31631, 31635, 31636, and 31638-31643. Code 31627 includes 3-dimensional reconstruction so it should not be reported with codes 76376 and 76377.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Policy Implementation/Update Information

2/16/10 New policy issued. Electromagnetic navigation bronchoscopy is considered **investigational** for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes. (adn)

2/1/11 Added statement under "Not Covered Section" to indicate: "Electromagnetic navigation bronchoscopy is considered **investigational** for the placement of fiducial markers. Added new CPT code 31626 under "Billing/Coding Section". Removed policy number. References added. (lpr)

4/12/11 Information in the Description and Policy Guidelines sections updated. Specialty Matched Consultant Advisory Panel review 3/30/11. No change to policy statement or medical coverage criteria. (adn)

3/30/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. Updated references and policy guidelines. No change to policy statement.(lpr)

4/16/13 Revised Policy Guidelines section. Specialty Matched Consultant Advisory panel review 3/20/2013. Reference added. No change to policy statement. (lpr)

5/13/14 Specialty Matched consultant advisory panel review meeting 4/30/14. No change to policy statement. Reference updated. Deleted CPT code 31626 from Billing/Coding section. Medical director review 4/2014. (lpr)

2/24/15 Reference added. (lpr)

4/28/15 Specialty Matched Consultant Advisory panel review 3/25/2015. No change to policy statement. (lpr)

4/29/16 Specialty Matched Consultant Advisory Panel review 3/30/2016. Updated Policy Guidelines section. No change to policy statement. (lpr)

7/26/16 Updated Policy Guidelines and Regulatory status sections. Reference added. No change to policy statement. (lpr)

9/15/17 Specialty Matched Consultant Advisory Panel review 3/29/2017. Coverage statement revised with medical necessity criteria. Updated Policy Guidelines section. References added. Senior Medical Director review 9/2017. (lpr)

4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (lpr)

7/27/18 Reference added. (lpr)

4/30/19 Specialty Matched Consultant Advisory Panel review 3/20/2019. Updated Regulatory Status. References added. No change to policy statement. (lpr)

4/28/20 Specialty Matched Consultant Advisory Panel review 3/31/2020. Policy guidelines updated. No change to policy statement. (eel)

12/31/20 Within "When Covered" section, clarified standard methods with "(e.g. peripheral nodule)". Added "diagnosis" to "When Covered" sections 3rd bullet point. Medical Director review. (bb)

5/18/21 Specialty Matched Consultant Advisory Panel review 3/2021. Regulatory Status and Policy guidelines updated. Reference added. Medical Director review 4/2021. No change to policy statement. (bb)

3/31/22 Specialty Matched Consultant Advisory Panel review 3/2022. Policy guidelines updated. References added. Medical Director review 3/2022. No change to policy statement (tt)