Electromagnetic Navigation Bronchoscopy

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%–24% 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.
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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, Minneapolis, 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.

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).

***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
Electromagnetic Navigation Bronchoscopy

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 bronchoscopic methods 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 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) who receive ENB with flexible bronchoscopy, the evidence includes meta-analyses, 1 randomized controlled trial (RCT), and a number of observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. The most recent meta-analysis, which included 17 studies, reported a large pooled positive likelihood ratio but a small negative likelihood ratio. The single RCT found higher a diagnostic yield when both ENB and endobronchial ultrasound (EBUS) were used compared with either intervention alone, but did not include a group without ENB or EBUS. Two uncontrolled studies of sequential use of ENB following failure of EBUS to locate lesions or result in a diagnosis found a moderate increase in diagnostic yield when ENB was used. Most published studies had small sample sizes and thus there is limited evidence on complications of the procedure and adverse effects (eg, pneumothorax). The data are also insufficient to identify potential patient selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, the evidence includes 1 RCT and observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. The RCT found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration (TNBA) than conventional TNBA. EBUS, which has been shown superior to conventional TNBA, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy. The evidence is insufficient to determine the effects of the technology on health outcomes.
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For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, the evidence includes 1 controlled study and several uncontrolled studies. Relevant outcomes are other test performance measures, health status measures, and treatment-related morbidity. The controlled study compared markers placed transcutaneously under computed tomography or fluoroscopic guidance or transbronchially with ENB. However, only 8 patients who had markers placed with ENB had data available. There are several case series, with sample sizes ranging from 9 to 64 patients, but comparative data are needed to draw conclusions about the safety and efficacy of ENB for fiducial marker placement. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 V1.2016 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, 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

Electromagnetic Navigation Bronchoscopy


Senior Medical Director Review 1/21/2010.


Specialty Matched Consultant Advisory Panel review 3-2012

Specialty Matched Consultant Advisory Panel review 3-2013


Specialty Matched Consultant Advisory Panel review 3/2015

Specialty Matched Consultant Advisory Panel review 3/2017


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*Ann Am Thorac Soc.* 2016 Dec;13(12):2223-2228. YIELD >96.8% and PTX rate 6.8%


Senior Medical Director review 9/2017

Specialty Matched Consultant Advisory Panel review 3/2018


Specialty Matched Consultant Advisory Panel review 3/2019


https://www.itnonline.com/content/auris-health-unveils-fda-cleared-monarch-platform-robotic-bronchoscopy

**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)
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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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.