

Corporate Medical Policy

Electromagnetic Navigation Bronchoscopy

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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. (Note that screening for lung cancer and whole-body CT tests for screening are considered investigational *). 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 6 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. Lung biopsy is the gold standard for diagnosing pulmonary nodules, but is an invasive procedure.

Recent advances in technology have led to enhancements that 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 laptop 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 on the InReach computer console 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. The steerable navigation catheter is placed at the same site as the virtual markers, and the position of each is marked using a foot pedal;
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 and the working guide is retracted. Once this occurs, any endoscopic tool 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.

Once the navigation catheter is in place, any endoscopic tool can be inserted through the channel in the catheter to the target. This includes insertion of 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.

In September 2004, the superDimension/Bronchus (superDimension Ltd, Herzliya, Israel) 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 determined that this device was substantially equivalent to existing bronchoscopic devices. It is indicated 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. The trade name of the device is the inReach™ system; it is currently marketed in the United States by superDimension, Inc, Minneapolis, MN. An updated catheter system (Edge™) for use with the InReach system was cleared by the FDA through the 510(k) process in October 2010.

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™ Drive 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)

Related Policies

* Refer to policies "Lung Cancer Screening, CT Scanning or Chest Radiographs" and "Whole Body Computed Tomography Scan as a Screening Test."

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****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 not provide coverage for Electromagnetic Navigation Bronchoscopy. It is considered investigational and BCBSNC does not cover investigational procedures.

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

Not applicable.

When Electromagnetic Navigation Bronchoscopy is not covered

Electromagnetic navigation bronchoscopy is considered **investigational** for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes.

Electromagnetic navigation bronchoscopy is considered **investigational** for the placement of fiducial markers.

Policy Guidelines

Electromagnetic navigation bronchoscopy uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. Overall, data are insufficient to determine the risks and benefits of ENB compared to standard approaches to diagnose peripheral lesions. The evidence on ENB for diagnosis of pulmonary lesions consists largely of case series. The single published controlled study compared ENB to another novel diagnostic approach, EBUS, rather than to standard bronchoscopy or transthoracic needle aspiration. Diagnostic yield, the ability to determine a conclusive diagnosis, of ENB per lesion in the available studies ranged from 57% to 75%; a recent meta-analysis found a pooled diagnostic yield of 67%. Due to the small number of patients in individual studies, there is limited evidence on complications from the procedure and adverse effects such as pneumothorax. The data are also insufficient to identify which patients might benefit from ENB. Eligibility criteria of existing studies were variable, and in some cases, not well-defined; it is not clear whether this would be most appropriate as a first-line or second-line diagnostic approach.

There are less data on the potential use of ENB in biopsy of mediastinal lymph nodes.

Insufficient data are available on the safety and efficacy of ENB used for fiducial marker placement. Only one small study that compared ENB to another method of fiducial marker placement was identified.

In 2011, the British Thoracic Society published a guideline on advanced diagnostic and therapeutic flexible bronchoscopy in adults. The guideline included the following recommendation: "Electromagnetic bronchoscopy may be considered for the biopsy of peripheral lesions or to guide TBNA for sampling mediastinal lymph nodes." This was a "Grade D" recommendation, meaning that it is based on non-analytic studies, e.g., case series or expert opinion, or based on extrapolated data from

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observational studies.

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: 31626, 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

Rivera MP, Mehta AC. Initial diagnosis of lung cancer. *Chest* 2007; 132(3 suppl):131S-148S.

Tape TG. Solitary pulmonary nodule. In Black ER, Bordley DR, Tape TG et al., eds. *Diagnostic Strategies for Common Medical Problems*, second ed. Philadelphia, PA: American College of Physicians, 1999.

Alberts WM. Diagnosis and management of lung cancer: executive summary: ACCP evidence-based clinical practice guidelines (2nd edition). *Chest* 2007; 132(3 suppl):1S-19S.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.122, 11/12/09

Senior Medical Director Review 1/21/2010.

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Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-analysis of guided bronchoscopy for the evaluation of the pulmonary nodule. *Chest* 2011; Epub ahead of print.

Du Rand IA, Barber PV, Goldring J et al. British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. *Thorax* 2011; 66(Suppl 3):iii1-21.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.122, 1/12/12

Specialty Matched Consultant Advisory Panel review 3-2012

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

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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)

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.