Protocol

Electromagnetic Navigation Bronchoscopy

Medical Benefit		**Effective Date**: 04/01/13	**Next Review Date**: 01/15
Preauthorization	Yes	**Review Dates**: 09/10, 09/11, 01/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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 be biopsied 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 diagnose 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. (1, 2)

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. (1)

Another proposed enhancement to standard bronchoscopy is electromagnetic navigation bronchoscopy (ENB). This technology uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. The InReach™ system was the first ENB system cleared for marketing by the U.S. Food and Drug Administration (FDA). The three phases of the procedure using the InReach system are as follows:

1. Planning phase: 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 petal;
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 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 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 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 device is 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 Protocols

Real-Time Intra-Fraction Target Tracking During Radiation Therapy

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Policy (Formerly Corporate Medical Guideline)

Electromagnetic navigation bronchoscopy (ENB) is considered **medically necessary** in patients with solitary pulmonary nodules in which:

- malignancy is reasonably suspected and
- it has been determined that a tissue diagnosis is required and
- percutaneous lung biopsy is considered high risk and low probability for diagnostic yield and
- standard bronchoscopy and/or endobronchial ultrasound (EBUS) are considered low probability for diagnostic yield.

ENB is considered **medically necessary** in patients with an identified lung lesion(s) and a coexisting cancer in whom:

- further determination of the lung lesion may impact the staging of the primary malignancy, and the treatment and
- percutaneous lung biopsy is considered high risk and low probability for diagnostic yield and
- standard bronchoscopy and/or EBUS are considered low probability for diagnostic yield.

Electromagnetic navigation bronchoscopy is considered **medically necessary** for the placement of fiducial markers in patients who are to undergo radiotherapeutic treatment of malignant solitary pulmonary nodules when:

- they are not surgical candidates and radiation treatment is the preferred treatment and
- it is determined that the location of the nodules makes placement of fiducial markers by a transthoracic approach likely to be associated with high risk of developing significant pneumothorax.

Electromagnetic navigation bronchoscopy is considered **medically necessary** for the placement of fiducial markers to help localize a nodule by fluoroscopy during thorascopic excision that would otherwise not be palpable without a thoracotomy.

All other uses of ENB are considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Rivera MP, Mehta AC, American College of Chest P. Initial diagnosis of lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 2007; 132(3 Suppl):131S-48S.

2. Tape TG. Solitary Pulmonary Nodule. In Black ER et al; eds. Diagnostic strategies for common medical problems, 2nd edition. Philadelphia, PA: American College of Physicians; 1999.
3. Eberhardt R, Anantham D, Ernst A et al. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized controlled trial. Am J Respir Crit Care Med 2007; 176(1):36-41.
4. Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-analysis of guided bronchoscopy for the evaluation of the pulmonary nodule. Chest 2012; 142(2):385-93.
5. Brownback KR, Quijano F, Latham HE et al. Electromagnetic navigational bronchoscopy in the diagnosis of lung lesions. J Bronchology Interv Pulmonol 2012; 19(2):91-7.
6. Wilson DS, Bartlett BJ. Improved diagnostic yield of bronchoscopy in a community practice: combination of electromagnetic navigation system and rapid on-site evaluation. J Bronchology Interv Pulmonol 2007; 14(4):227-32.
7. Eberhardt R, Anantham D, Herth F et al. Electromagnetic navigation diagnostic bronchoscopy in peripheral lung lesions. Chest 2007; 131(6):1800-5.
8. Jensen KW, Hsia DW, Seijo LM et al. Multicenter experience with electromagnetic navigation bronchoscopy for the diagnosis of pulmonary nodules. J Bronchology Interv Pulmonol 2012; 19(3):195-9.
9. Lamprecht B, Porsch P, Wegleitner B et al. Electromagnetic navigation bronchoscopy (ENB): Increasing diagnostic yield. Respir Med 2012; 106(5):710-5.
10. Seijo LM, de Torres JP, Lozano MD et al. Diagnostic yield of electromagnetic navigation bronchoscopy is highly dependent on the presence of a Bronchus sign on CT imaging: results from a prospective study. Chest 2010; 138(6):1316-21.
11. Kupelian PA, Forbes A, Willoughby TR et al. Implantation and stability of metallic fiducials within pulmonary lesions. Int J Radiat Oncol Biol Phys 2007; 69(3):777-85.
12. Anantham D, Feller-Kopman D, Shanmugham LN et al. Electromagnetic navigation bronchoscopy-guided fiducial placement for robotic stereotactic radiosurgery of lung tumors: a feasibility study. Chest 2007; 132(3):930-5.
13. Schroeder C, Hejal R, Linden PA. Coil spring fiducial markers placed safely using navigation bronchoscopy in inoperable patients allows accurate delivery of CyberKnife stereotactic radiosurgery. J Thorac Cardiovasc Surg 2010; 140(5):1137-42.
14. 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.
15. Alberts WM, American College of Chest P. Diagnosis and management of lung cancer executive summary: ACCP evidence-based clinical practice guidelines (2nd Edition). Chest 2007; 132(3 Suppl):1S-19S.