

**EFFECTIVE DATE:** 10|01|2015  
**POLICY LAST UPDATED:** 10|02|2018

## OVERVIEW

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a 3-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.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### BlueCHiP for Medicare

Electromagnetic navigation bronchoscopy is not covered for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Electromagnetic navigation bronchoscopy is considered not medically necessary for the placement of fiducial markers as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Commercial Products

Electromagnetic navigation bronchoscopy is considered not medically necessary for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes as the evidence is insufficient to determine the effects of the technology on health outcomes.

Electromagnetic navigation bronchoscopy is considered not medically necessary for the placement of fiducial markers as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for not covered/not medically necessary benefits/coverage.

## BACKGROUND

### PULMONARY NODULES

Pulmonary nodules are identified on plain chest radiographs, or chest computed tomography scans. Although most nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when it is diagnosed later.

### Diagnosis

The method used to diagnose lung cancer depends on a number of factors, including lesion size, shape, location, as well as the clinical history and status of the patient. Peripheral lung lesions and solitary pulmonary nodules (most often defined as asymptomatic nodules <6 mm) are more difficult to evaluate than larger,

centrally located lesions. There are several options for diagnosing malignant disease, but none of the methods is ideal. 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 evaluate 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 (<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% to 25% of patients, and 5% to 14% require insertion of a chest tube. Positron emission tomography scans are also highly sensitive for evaluating pulmonary nodules yet may miss lesions less than 1 cm in size. A lung biopsy is the criterion 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.

#### Marker Placement

Another proposed enhancement to standard bronchoscopy is ENB. ENB is intended to enhance standard bronchoscopy by providing a 3-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. 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.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, the evidence is insufficient to determine the effects of the technology on health outcomes. For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, the evidence is insufficient to determine the effects of the technology on health outcomes.

#### **CODING**

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

- 31626 Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed; with placement of fiducial markers, single or multiple
- 31627 Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed; with computer assisted, image-guided navigation (List separately in addition to code for primary procedure)
- C9751 Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s) (New Code Effective 1/1/2019)

#### **RELATED POLICIES**

Not applicable

#### **PUBLISHED**

Provider Update, November/December 2018  
Provider Update, January 2018  
Provider Update, January 2017  
Provider Update, August 2015

## REFERENCES

1. Rivera MP, Mehta AC, American College of Chest P. Initial diagnosis of lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition). *Chest*. Sep 2007;132(3 Suppl):131S-148S. PMID 17873165
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. Wiener RS, Wiener DC, Gould MK. Risks of transthoracic needle biopsy: how high? *Clin Pulm Med*. Jan 01 2013;20(1):29-35. PMID 23525679
4. Zhang W, Chen S, Dong X, et al. Meta-analysis of the diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules. *J Thorac Dis*. May 2015;7(5):799-809. PMID 26101635
5. Gex G, Pralong JA, Combescure C, et al. Diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules: a systematic review and meta-analysis. *Respiration*. 2014;87(2):165-176. PMID 24401166
6. 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*. Jul 1 2007;176(1):36-41. PMID 17379850
7. Khandhar SJ, Bowling MR, Flandes J, et al. Electromagnetic navigation bronchoscopy to access lung lesions in 1,000 subjects: first results of the prospective, multicenter NAVIGATE study. *BMC Pulm Med*. Apr 11 2017;17(1):59. PMID 28399830
8. Ost DE, Ernst A, Lei X, et al. Yield and complications of bronchoscopy for peripheral lung lesions. results of the AQuIRE Registry. *Am J Respir Crit Care Med*. Jan 1 2016;193(1):68-77. PMID 26367186
9. Chee A, Stather DR, Maceachern P, et al. Diagnostic utility of peripheral endobronchial ultrasound with electromagnetic navigation bronchoscopy in peripheral lung nodules. *Respirology*. Jul 2013;18(5):784-789. PMID 23521707
10. Steinfort DP, Bonney A, See K, et al. Sequential multimodality bronchoscopic investigation of peripheral pulmonary lesions. *Eur Respir J*. Feb 2016;47(2):607-614. PMID 26541529
11. Diken OE, Karnak D, Ciledag A, et al. Electromagnetic navigation-guided TBNA vs conventional TBNA in the diagnosis of mediastinal lymphadenopathy. *Clin Respir J*. Apr 2015;9(2):214-220. PMID 25849298
12. 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):227-232.
13. Kupelian PA, Forbes A, Willoughby TR, et al. Implantation and stability of metallic fiducials within pulmonary lesions. *Int J Radiat Oncol Biol Phys*. Nov 1 2007;69(3):777-785. PMID 17606334
14. 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*. Sep 2007;132(3):930-935. PMID 17646225
15. 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*. Nov 2010;140(5):1137-1142. PMID 20850809
16. Bolton WD, Richey J, Ben-Or S, et al. Electromagnetic navigational bronchoscopy: a safe and effective method for fiducial marker placement in lung cancer patients. *Am Surg*. Jul 2015;81(7):659-662. PMID 26140883
17. Nabavizadeh N, Zhang J, Elliott DA, et al. Electromagnetic navigational bronchoscopy-guided fiducial markers for lung stereotactic body radiation therapy: analysis of safety, feasibility, and interfraction stability. *J Bronchology Interv Pulmonol*. Apr 2014;21(2):123-130. PMID 24739685

18. Minnich DJ, Bryant AS, Wei B, et al. Retention rate of electromagnetic navigation bronchoscopic placed fiducial markers for lung radiosurgery. *Ann Thorac Surg.* Oct 2015;100(4):1163-1165; discussion 1165-1166. PMID 26228602
19. Rong Y, Bazan JG, Sekhon A, et al. Minimal inter-fractional fiducial migration during image-guided lung stereotactic body radiotherapy using superlock nitinol coil fiducial markers. *PLoS One.* 2015;10(7):e0131945. PMID 26158847
20. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-small cell lung cancer. Version 6.2017. 2017; [http://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed May 31, 2017.
21. Rivera MP, Mehta AC, Wahidi MM. Establishing the diagnosis of lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest.* May 2013;143(5 Suppl):e142S-165S. PMID 23649436
22. Du Rand IA, Barber PV, Goldring J, et al. British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. *Thorax.* Nov 2011;66 Suppl 3:iii1-21. PMID 21987439

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