MEDICAL POLICY

Excellus
An independent licensee of the Blue Cross Blue Shield Association

Medical Policy Title	**Electromagnetic Navigation Bronchoscopy**
Policy Number	**6.01.40**
Current Effective Date	May 15, 2025
Next Review Date	January 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Electromagnetic navigation bronchoscopy (ENB) is considered **medically appropriate** in **ANY** of the following circumstances:

   A. Highly suspicious solitary pulmonary nodule and **ONE** (1) of the following:

      1. Pulmonary nodule is inaccessible by standard bronchoscopic methods;
      2. Patient is not a candidate for transthoracic needle biopsy;
      3. Poses an unacceptable risk (e.g., has bullous lung disease, diffuse emphysema) for a more invasive diagnostic procedure;

   B. Lung lesion(s) and a co-existing cancer, and further determination of the lung lesion will impact staging of the primary tumor and, treatment plan;

   C. When placement of fiducial markers is required when **ALL** of the following criteria are met:

      1. Patient is a non-surgical candidate; and
      2. Patient has elected to undergo radiation therapy.

II. ENB for any other indication is considered **investigational**.

RELATED POLICIE(S)

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

There are no applicable policy guidelines.

DESCRIPTION

Electromagnetic navigation bronchoscopy (ENB) combines simultaneous CT virtual bronchoscopy with real-time fiberoptic 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. ENB during flexible bronchoscopy has been proposed as a method to further increase the diagnostic yield of bronchoscopy in the diagnosis of peripheral and mediastinal

lung lesions, by allowing the physician to place endobronchial accessories (e.g., forceps, brush, needle) in areas of the lung that would be hard to reach otherwise.

ENB is also utilized for placement of dye markers in peripheral lung lesions and near the pleura surface, to provide guidance during video-assisted thoracoscopic surgery; and for placement of radiosurgical markers transbronchially, to help radiation oncologists plan and treat patients with external beam radiation.

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography (CT) scans. Although most of these nodules are benign, some are malignant; early diagnosis of lung cancer is desirable because of the poor prognosis when it is diagnosed later in the disease course. The method used to diagnose lung cancer depends upon multiple factors, including lesion size, location, clinical history and status of the patient. Flexible bronchoscopy is a minimally invasive procedure, it 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 1.5cm in diameter, the sensitivity may be as low as 10%. Peripheral lung lesions and solitary pulmonary nodules (SPN) 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.

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 has the disadvantage of exposing the patient and staff to radiation. Endobronchial ultrasound (EBUS) by radial probes, previously used in the peri-operative 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.

SUPPORTIVE LITERATURE

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.

Folch et al. (2021) presented the 24-month results of the NAVIGATE study. The study is a large multicenter, prospective, single-arm, and nonrandomized. It was used to present usage patterns and ENB-aided diagnostic yield with prospective, independently verified 24-month follow-up. They studied subjects presenting with lung lesions requiring evaluation and suitable for ENB. A total of 1388 subjects were enrolled for lung lesion biopsy (95.7%, 1329 of 1388), fiducial marker placement (19.6%), dye marking (1.7%) or lymph node biopsy (2.6%). Concurrent endobronchial ultrasound-guided staging occurred in 456 subjects. This diagnostic yield was 67.8%, sensitivity for malignancy was 62.6%. Among the 1329 subjects undergoing ENB-guided biopsy, 94.8% (1260 of 1329) had navigation completed and tissue obtained. Malignancy was diagnosed in 42.6% and 57.4% were negative for malignancy on the basis of the ENB-aided procedure. After evaluation over 24 months, there were no false positives. Of the 723 cases initially considered negative for malignancy, 285 were

true negative, 321 were false negative, and 117 remained indeterminate at 24 months. Even with a diverse cohort and differences in procedural techniques, ENB demonstrates low complications and a 67.8% diagnostic yield while allowing biopsy, staging, fiducial placement, and dye marking in a single procedure.

PROFESSIONAL GUIDELINE(S)

National Comprehensive Cancer Network (NCCN) clinical practice guideline on non-small-cell lung cancer version 11.2024 states that the strategy for diagnosing lung cancer and that it should be individualized, and the least invasive biopsy with the highest diagnostic yield is preferred as the initial diagnostic study.

- For patients with central masses and suspected endobronchial involvement, bronchoscopy is preferred.
- Patients with pulmonary nodules may benefit from either navigational bronchoscopy (including robotic), radial endobronchial ultrasound (EBUS) or transthoracic needle aspiration (TTNA).
- Patients with suspected nodal disease should be biopsied by EBUS, endoscopic ultrasound (EUS), navigational bronchoscopy or mediastinoscopy.

In the most current guidelines from 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 is grade 1C, defined as "strong recommendation, low- or very-low-quality evidence."

REGULATORY STATUS

Not applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed; with placement of fiducial markers, single or multiple

Code	Description
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[s])

HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Alberts WM, et al. Diagnosis and management of lung cancer executive summary: ACCP evidenced-based clinical practice guidelines (2nd edition). Chest. 2007;132(3 Suppl):1S-19S.

Anantham D, et al. Electromagnetic navigation bronchoscopy-guided fiducial placement for robotic stereotactic radiosurgery of lung tumors: a feasibility study. Chest. 2007 Sep;132(3):930-5.

Awais O, et al. Electromagnetic navigation bronchoscopy-guided dye marking for thoracoscopic resection of pulmonary nodules. Ann Thorac Surg. 2016 July;102(1):223-229.

Bechara R, et al. Electromagnetic navigation bronchoscopy. Future Oncol. 2011 Jan;7(1):31-6.

Bondue B, et al. High diagnostic yield of electromagnetic navigation bronchoscopy performed under cone beam CT guidance: results of a randomized Belgian monocentric study. BMC Pulm Med. 2023 May 27;23(1):185.

Bowling MR, et al. Fiducial marker placement with electromagnetic navigation bronchoscopy: a subgroup analysis of the prospective, multicenter NAVIGATE study. Ther Adv Respir Dis. 2019,13:1–11.

Chen JY, et al. Diagnostic yield using electromagnetic navigation bronchoscopy for peripheral pulmonary nodules <2 cm. Ther Adv Respir Dis. 2024 Jan-Dec;18:17534666241249150.

Detterbeck FC, et al. Screening for lung cancer: Diagnosis and management of lung cancer, 3rd ed: American college of chest physicians evidence-based clinical practice guidelines. Chest. 2013 May;143(5 Suppl):e78S-e92S.

Du Rand IA, et al. Summary of the British Thoracic Society guidelines for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax. 2011 Nov;66(11):1014-5.

Folch EE, et al. NAVIGATE 24-Month Results: Electromagnetic navigation bronchoscopy for pulmonary lesions at 37 centers in Europe and the United States. J Thorac Onc. 2022 Apr;17(4):519-531.

Gex G, 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.

Jensen KW, et al. Multicenter experience with electromagnetic navigation bronchoscopy for the diagnosis of pulmonary nodules. J Bronchology Interv Pulmonol. 2012 Jul;19(3):195-9.

Lee B, et al. Optimal approach for diagnosing peripheral lung nodules by combining electromagnetic navigation bronchoscopy and radial probe endobronchial ultrasound. Thorac Cancer. 2024 Jul;15(21):1638-1645.

Mariolo AV, et al. Electromagnetic navigation bronchoscopy localization of lung nodules for thoracoscopic resection. J Thorac Dis. 2021 Jul;13(7):4371-4377.

National Comprehensive Cancer Network (NCCN) [Internet]. Non-small cell lung cancer Version 11.2024. 2024 Oct 15 [accessed 2024 Dec 12]. Available from: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

Paez R,et al. Robotic versus Electromagnetic bronchoscopy for pulmonary LesIon AssessmeNT: the RELIANT pragmatic randomized trial. Trials. 2024 Jan 19;25(1):66.

Qian K, et al. Efficiency of electromagnetic navigation bronchoscopy and virtual bronchoscopic navigation. Ann Thorac Surg. 2020;109:1731-40.

Rivera MP, et al. Initial diagnosis of lung cancer: ACCP evidenced-based clinical practice guidelines (2nd edition). Chest. 2007 Sep;132(3 Suppl):131S-48S.

Song JW, et al. Electromagnetic navigation bronchoscopy-guided dye marking for localization of pulmonary nodules. Ann Thorac Surg. 2022 May;113(5):1663-1669.

Wang Memoli JS, et al. Meta-analysis of guided bronchoscopy for the evaluation of the pulmonary nodule. Chest. 2012 Aug;142(2):385-393.

Wang L, et al. Electromagnetic navigational bronchoscopy directed dye marking for locating pulmonary nodules. Postgrad Med J. 2020 Feb;96:674-679.

Yanagiya M, et al. A meta-analysis of preoperative bronchoscopic marking for pulmonary nodules. European Journal of Cardio-Thoracic Surgery. 2020 Apr;58:40-50.

Zeng C, et al. Application of electromagnetic navigation bronchoscopy-guided microwave ablation in multiple pulmonary nodules: a single-centre study. Eur J Cardiothorac Surg. 2022 Sep;62(4):ezac071.

Zhang W, et al. Meta-analysis of the diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules. J Thorac Dis. 2015 May;7(5):799-809.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Electromagnetic navigation bronchoscopy is not addressed in National or Regional CMS coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

04/16/12, 03/21/13, 03/20/14, 03/19/15, 02/18/16, 02/16/17, 01/18/18, 01/17/19, 01/16/20, 01/21/21, 01/20/22, 01/19/23, 01/18/24, 01/23/25

Date	Summary of Changes
01/23/25	• Annual review. Policy criteria for transthoracic needle biopsy as clarification to standard or care.
01/01/25	• Summary of changes tracking implemented.
04/16/12	• Original effective date