



MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY
Policy Number	6.01.40
Category	Technology Assessment
Effective Date	04/21/11
Revised Date	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
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, electromagnetic navigation bronchoscopy has been medically proven to be effective and is considered **medically appropriate** in any of the following circumstances:
- Patient has a highly suspicious solitary pulmonary nodule that is deemed inaccessible by standard bronchoscopic methods or when standard methods have failed;
 - Patient has a highly suspicious solitary pulmonary nodule and poses an unacceptable risk (e.g., has bullous lung disease, diffuse emphysema) for a more invasive diagnostic procedure;
 - Patient has an identified lung lesion(s) and a co-existing cancer, and further determination of the lung lesion will impact staging of the primary tumor and, thus, impact the treatment plan; or
 - Placement of fiducial markers is required for patient who is not a candidate for surgical intervention and who has elected to undergo radiation therapy.
- II. Based upon our criteria and assessment of peer-reviewed literature, use of electromagnetic navigation bronchoscopy for any other indication is considered **investigational**.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

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. 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%. 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.

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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 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.

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. Electromagnetic navigation bronchoscopy 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 has also been proposed 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.

RATIONALE

In September 2004, the SuperDimension®/Bronchus inReach™ (superDimension Ltd, Herzliya, Israel) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing bronchoscopic devices. It is indicated for displaying images of the tracheobronchial tree, which aids physicians in guiding endoscopic tools in the pulmonary tract. The trade name of the device is the inReach™ system; it is currently marketed in the United States by superDimension, Inc., Minneapolis, MN. In December 2009, a second ENB system, the ig4™ EndoBronchial System, received FDA clearance through the 510(k) process. This is also known as the SpiN Drive™ system by Veran Medical (St. Louis, MO). Several additional navigation software-only systems have been cleared for marketing by the FDA through the 510(k) process. These include: the LungPoint virtual bronchoscopic navigation (VPN) system (Broncus Technologies, Mountain View, CA) in 2008, and the bf-NAVI virtual bronchoscopic navigation (VPN) system (Emergo Group, Austin, TX) in 2010.

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. 2020 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. Patients with suspected nodal disease should be biopsied by EBUS, EUS, navigational bronchoscopy or mediastinoscopy.

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 is grade 1C, defined as "Strong recommendation, low- or very-low-quality evidence."

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

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- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
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[s])

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HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

Code	Description
Multiple diagnosis codes	

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*Key Article

KEY WORDS

ENB, electromagnetic navigation bronchoscopy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, electromagnetic navigation bronchoscopy is not addressed in National or regional CMS coverage determinations or policies.