

SUBJECT: ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY	EFFECTIVE DATE: 04/21/11 REVISED DATE: 04/16/12, 03/21/13, 03/20/14
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• *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*

• *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*

• *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

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:
 - A. Patients with a highly suspicious solitary pulmonary nodule that is deemed inaccessible by standard bronchoscopic methods or when standard methods have failed;
 - B. Patients with a highly suspicious solitary pulmonary nodule who pose an unacceptable risk (e.g., bullous lung disease, diffuse emphysema) for a more invasive diagnostic procedure;
 - C. Patients with an identified lung lesion(s) and a co-existing cancer in whom further determination of the lung lesion will impact staging of the primary tumor and thus impact the treatment plan; or
 - D. Placement of fiducial markers in patients who are not candidates for surgical intervention and who have 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 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. 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.

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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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 in order 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 (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 that 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, 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.

CODES: Number Description

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

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.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	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)

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HCPCS: No specific codes

ICD9: Multiple diagnosis codes

ICD10: Multiple diagnosis codes

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* key article

KEY WORDS:

ENB, electromagnetic navigation bronchoscopy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) and Article for electromagnetic navigation bronchoscopy. Please refer to the following LCD website for Medicare Members: http://apps.ngsmedicare.com/lcd/LCD_L30171.htm