

**Contractor Name**

Wisconsin Physicians Service (WPS)

**Contractor Number**

00951, 00952, 00953, 00954  
05101, 05201, 05301, 05401,  
05102, 05202, 05302, 05402,  
52280

**Contractor Type**

Carrier B  
Fiscal Intermediary A  
MAC A  
MAC B

**LCD Database ID Number****LCD Version Number****LCD Title**

Electromagnetic Navigation Bronchoscopy (ENB)

**Contractor's Determination Number**

PULM-007

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**CMS National Coverage Policy****Primary Geographic Jurisdiction**

**Carrier B:** Wisconsin, Illinois, Michigan, Minnesota

**Fiscal Intermediary A:** Alaska, Alabama, Arizona, Arkansas, California - Entire State, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri - Entire State, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, American Samoa, Guam, Northern Mariana Islands, U.S. Virgin Islands

**MAC A/B:** Iowa, Missouri, Nebraska, Kansas

**Secondary Geographic Jurisdiction****Oversight Region**

## **Original Determination Effective Date**

## **Revision Effective Date**

## **Indications and Limitations of Coverage and/or Medical Necessity**

### **Indications:**

Despite spectacular medical advances in the last 50 years, lung cancer causes more deaths than any other cancer in both men and women. It is now the most common form of cancer diagnosed in the United States and a major cause of death, accounting for 14% of all cancers and 31% all cancer deaths in males.

Electromagnetic navigation bronchoscopy systems are designed to biopsy peripheral lung lesions by an endobronchial route using a real-time navigation system. The navigation system tracks positioning of the bronchoscope tip on a three-dimensional (3-D) map of the inner lung constructed from a recent computed tomography (CT) lung scan. The navigation system is inserted into the working channel of a bronchoscope and uses CT scanning and low frequency electromagnetic field guiding technology along with a standard steerable fiber optic camera to re-create the 3-D mapping onto previously defined anatomical landmarks. When peripheral foci are reached, an extended working channel is locked in position through which tissues samples are biopsied.

### **The ENB system consists of four essential components:**

1. Computer software that creates a three-dimensional (3D), virtual bronchoscopy reconstruction from CT images;
2. An electromagnetic location board that emits a low-dose electromagnetic field;
3. A sensor probe that has an 8-way steering mechanism and is locatable within the electromagnetic field, and
4. An extended working channel (EWC) that when secured enables the placement of the bronchoscopic tools to the lung periphery.

The digitized information from the patient's CT scan is imported into the electromagnetic navigation system where axial, coronal and sagittal views of the chest and virtual endoscopy images are reconstructed. Anatomic landmarks are identified as coordinates on the corresponding CT as well as on the virtual bronchoscopy image (planning). The same identifiable landmarks are then used during real-time bronchoscopy in order to relate the CT data to the actual anatomy. When these points were touched with the sensor, they were simultaneously recorded by the navigation system (registration). After registration, navigation is performed with simultaneous advancement of the steerable probe toward the target and directing the steerable probe to the lesion.

The ENB system enables real-time navigation guidance within the lungs to endobronchially invisible targets and subsequent biopsy through the extending working channel. This procedure can also be used for the bronchoscopic placement of fiducial markers with ENB guidance. These markers can facilitate treatment localization for stereotactic radiosurgery in patients with early-stage bronchogenic carcinoma who are otherwise unfit for surgical resection.

Electromagnetic Navigation for Bronchoscopy will be considered medically necessary for the following conditions:

### **Solitary Pulmonary Nodule:**

Patients identified with Solitary Pulmonary Nodules in which malignancy is reasonably suspected and it has been determined that a tissue diagnosis is required, and

- the lesion is poorly accessible by standard bronchoscopy, or
- a more invasive procedure for diagnosis and/or staging pose a significant risk, i.e. high pneumothorax risk, bullous lung disease, diffuse emphysema, etc.

### **Lung Lesion with a Coexisting Cancer:**

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 thus the treatment.

### **Placement of Fiducial markers:**

- Fiducial marker placement will be considered medically necessary when a brushing, washing, aspirate or biopsy shows a malignancy or high suspicion of a malignancy and the patients is considered a candidate for stereotactic radiosurgery.

### **Limitations:**

Electromagnetic Navigation for Bronchoscopy is not considered medically reasonable and necessary when:

- The patient has a solitary pulmonary nodule that is stable on imaging tests for at least two years,
- The patient has a solitary pulmonary nodule that is calcified in a clearly benign pattern,
- The patient has a low pretest probability of malignancy (<30 to 40%) and an indeterminate solitary pulmonary nodule that measures at least 8 to 10 mm in diameter, and the lesion is not hypermetabolic by FDG-PET imaging, or does not enhance .15 HU on dynamic contrast CT.
- CT scan indicates the lesion is accessible by a standard flexible bronchoscopy.

The diagnostic yield of ENB may be affected by CT-to-body divergence rather than the size or location of the lesion. The ENB yield was found to be significantly lower when CT-to-body divergence was 10 mm.

### **Bill Type Codes**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

11x Hospital-inpatient (including Part A)

13x Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)

85x Special facility or ASC surgery-rural primary care hospital (eff 10/94)

### **Revenue Codes**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination.

Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Revenue codes 096X, 097X and 098X are to be used only by Critical Access Hospitals (CAHs) choosing the optional payment method (also called Option 2 or Method 2) and only for services performed by physicians or practitioners who have reassigned their billing rights. When a CAH has selected the optional payment method, physicians or other practitioners providing professional services at the CAH

may elect to bill their carrier or Part B MAC, or assign their billing rights to the CAH. When professional services are reassigned to the CAH, the CAH must bill the FI, or Part A MAC using revenue codes 096X, 097X or 098X.

- 0360 Operating room services-general classification
- 0361 Operating room services-minor surgery
- 0490 Ambulatory surgical care-general classification
- 0960 Professional fees-general classification
- 0981 Professional fees-emergency room
- 0982 Professional fees-outpatient services
- 0983 Professional fees-clinic

**CPT/HCPCS Codes**

31899 UNLISTED PROCEDURE, TRACHEA, BRONCHI

76499 UNLISTED DIAGNOSTIC PROCEDURE

**Note**

76499 is used to indicate planning, including 3-D reconstruction of CT and mapping of target lesion or lymph node

31899 is used to indicate the use of electromagnetic image-guided navigation bronchoscopy (ENB)

**Does the CPT 30% Rule Apply**

No

**ICD-9 Codes that Support Medical Necessity**

Note: ICD-9 codes must be coded to the highest level of specificity.

162.3	MALIGNANT NEOPLASM OF UPPER LOBE BRONCHUS OR LUNG
162.4	MALIGNANT NEOPLASM OF MIDDLE LOBE BRONCHUS OR LUNG
162.5	MALIGNANT NEOPLASM OF LOWER LOBE BRONCHUS OR LUNG
162.8	MALIGNANT NEOPLASM OF OTHER PARTS OF BRONCHUS OR LUNG
162.9	MALIGNANT NEOPLASM OF BRONCHUS AND LUNG UNSPECIFIED
197.0	SECONDARY MALIGNANT NEOPLASM OF LUNG
212.3	BENIGN NEOPLASM OF BRONCHUS AND LUNG
518.89	OTHER DISEASES OF LUNG , NOT ELSEWHERE
793.1	NONSPECIFIC ABNORMAL FINDINGS ON RADIOLOGICAL AND OTHER EXAMINATION OF LUNG FIELD

**Diagnoses that Support Medical Necessity**

Not applicable

**ICD-9 Codes that DO NOT Support Medical Necessity**

Not applicable

**Diagnoses that DO NOT Support Medical Necessity**

Not applicable

**Documentation Requirements**

The patient's medical record must contain documentation that fully supports the medical necessity for services outlined in the Indications and Limitations section of Coverage in this LCD. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures including past radiologic examinations. The medical record must also contain evidence that diagnostic and treatment alternatives have been discussed with the patient. Results of all testing should be shared with the referring physician. Documentation must be available to Medicare upon request.

### **Utilization Guidelines**

Electromagnetic Navigation for Bronchoscopy may be necessary for diagnosis and possible placement of fiducial markers in those patients diagnosed with cancer. The procedure will be covered only twice per patient per episode of care. Services exceeding this parameter will be considered not medically necessary.

### **Sources of Information and Basis for Decision**

Anantham, D, et al. Electromagnetic navigation bronchoscopy guided fiducial placement for robotic stereotactic radiosurgery of lung tumors – a feasibility study. *Chest* 2007;132: 930-935.

#### NGS Medical Policy Electromagnetic Navigational Bronchoscopy

Becker HD, Herth F, Ernst A, Schwarz Y; Bronchoscopic biopsy of peripheral lung lesions under electromagnetic guidance. *J Bronchol.* 2005; 12(1):9-13.

Eberhardt R, Anantham D, Ernst A, Feller-Kopman D, Herth F. Multimodality bronchoscopic diagnosis of peripheral lung lesions: A randomized controlled trial. *Am J Respir Crit Care Med*; 176:36-41.

Eberhardt R, Anantham D, Herth F, Feller-Kopman D, Ernst A. Electromagnetic navigation diagnostic bronchoscopy in peripheral lung lesions. *Chest.* 2007:1800-1805.

Gildea, TR, Mazzone PJ, Karnak D, Meziane M, Mehta AC. Electromagnetic navigation diagnostic bronchoscopy: A prospective study. *Am J Respir Crit Care Med*;174:982-989.

Gould, MK, et al. Evaluation of patients with pulmonary nodules: When is it cancer? ACCP evidence-based clinical practice guidelines (2nd Edition).*Chest.* 2007; 132:108-130

Greenlee RT, et al. Cancer statistics 2000. *CA Cancer J Clin.* 2000; 50:7–33

Harms W, Krempien R, Grehn C, Hensley F, Debus J, Becker, HD. *Strahlenther Onkol.* 2006;182:108-111.

Kupelian PA, et al. Implantation and stability of metallic fiducials within pulmonary lesions. *Int J Radiation Oncology Biol Phys.* 2007; 69(3):777–785.

Makris D, et al. Electromagnetic navigation diagnostic bronchoscopy for small peripheral lung lesions. *Eur Respir J.* 2007; 29: 1187-1192.

McLemore L, Ochran G, Kerley Endobronchial ultrasound and/or super dimension bronchoscopic placement of fiducial markers in malignant mediastinal lymph nodes (LN) and lung cancers (LC): A novel approach for highly selective external beam radiation therapy (RT). 14th World Congress for Bronchology;2006:57-62.

Schwarz Y, et al. Electromagnetic navigation during flexible bronchoscopy. *Interventional Pulmonology.* 2003:516-522.

Schwarz Y, Greif J, Becker, HD, Ernst A, Mehta A. real-time electromagnetic navigation bronchoscopy to peripheral lung lesions using overlaid CT images: The first human study. Chest. 2006; 129:988-994.  
Shulman L, Ost D. Advances in bronchoscopic diagnosis of lung cancer. Curr Opin Pulm Med; 13:271-277.

Weiser TS, Hyman K, Yun J, Litle V, Chin C, Swanson, SJ. Electromagnetic navigational bronchoscopy: A surgeon's perspective. Ann Thorac Surg. 2008; 85:S797-801.

Wilson D. Improved diagnostic yield of bronchoscopy in a community based hospital: Combination of electromagnetic navigation system and rapid on-site evaluation. J Bronchol. 2007; 14(4):227-232.

### **Advisory Committee Meeting Notes**

Meeting Date:

Wisconsin 9/25/09

Illinois 9/16/09

Michigan 9/09/09

Minnesota 09/24/09

J5 MAC 10/08/09

### **Open LCD meeting:**

08/19/09

### **Start Date of Comment Period**

10/08/09

### **End Date of Comment Period**

11/23/09

### **Start Date of Notice Period**

(Published)

### **Revision History Number/Explanation**

### **Last Reviewed On**

### **Related Documents**

NA

### **LCD Attachments**

None

### **Does this LCD contain a "Least Costly Alternative" Provision?**

No