LCD for Electromagnetic Navigation Bronchoscopy (ENB) (L30510)

Contractor Information

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

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

Contractor Type

Carrier- FI - MAC

LCD Information

LCD ID Number

L30510

LCD Title

Electromagnetic Navigation Bronchoscopy (ENB)

Contractor's Determination Number

PULM-007

AMA CPT / ADA CDT Copyright Statement

CMS National Coverage Policy

Oversight Region

Region V

Original Determination Effective Date

For services performed on or after 02/15/2010

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

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 which emits a low-dose electromagnetic field;
3. A steerable sensor probe that 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 indeterminant 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.

Coding Information

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.

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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

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])

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 CLASSIFIED
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

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not applicable

General Information

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.

Appendices

Utilization Guidelines

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

*- An asterisk indicates a revision to that section of the policy.

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the MAC contractor this policy was developed in cooperation with advisory groups which include representatives from various specialties, and adapted for the purpose of converting to MAC jurisdiction.

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

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

10/08/2009

End Date of Comment Period

11/23/2009

Start Date of Notice Period

01/01/2010

Revision History Number

Revision History Explanation

Reason for Change

Last Reviewed On Date

12/11/2009

Related Documents

This LCD has no Related Documents.

LCD Attachments

All Versions

Updated on 12/18/2009 with effective dates 02/15/2010 - N/A