

EFFECTIVE DATE: 10|01|2015
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OVERVIEW

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a 3-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs, so that suspicious lesions can undergo biopsy and to allow for placement of fiducial markers.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Electromagnetic navigation bronchoscopy is not covered for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Electromagnetic navigation bronchoscopy is considered not medically necessary for the placement of fiducial markers as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Electromagnetic navigation bronchoscopy is considered not medically necessary for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes as the evidence is insufficient to determine the effects of the technology on health outcomes.

Electromagnetic navigation bronchoscopy is considered not medically necessary for the placement of fiducial markers as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for not covered/not medically necessary benefits/coverage.

BACKGROUND

PULMONARY NODULES

Pulmonary nodules are identified on plain chest radiographs, or chest computed tomography scans. Although most nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when it is diagnosed later.

Diagnosis

The method used to diagnose lung cancer depends on a number of factors, including lesion size, shape, location, as well as the clinical history and status of the patient. Peripheral lung lesions and solitary pulmonary nodules (most often defined as asymptomatic nodules <6 mm) are more difficult to evaluate than larger,

centrally located lesions. There are several options for diagnosing malignant disease, but none of the methods is ideal. Sputum cytology is the least invasive approach. Reported sensitivity rates are relatively low and vary widely across studies; sensitivity is lower for peripheral lesions. Sputum cytology, however, has a high specificity; and a positive test may obviate the need for more invasive testing. Flexible bronchoscopy, a minimally invasive procedure, is an established approach to evaluate 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 (<1.5 cm in diameter), the sensitivity may be as low as 10%. The diagnostic accuracy of transthoracic needle aspiration for solitary pulmonary nodules tends to be higher than that of bronchoscopy; the sensitivity and specificity are both approximately 94%. A disadvantage of transthoracic needle aspiration is that a pneumothorax develops in 11% to 25% of patients, and 5% to 14% require insertion of a chest tube. Positron emission tomography scans are also highly sensitive for evaluating pulmonary nodules yet may miss lesions less than 1 cm in size. A lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure.

Recent advances in technology 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.

Marker Placement

Another proposed enhancement to standard bronchoscopy is ENB. ENB is intended to enhance standard bronchoscopy by providing a 3-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs. Once the navigation catheter is in place, any endoscopic tool can be inserted through the channel in the catheter to the target. This includes insertion of transbronchial forceps to biopsy the lesion. In addition, the guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guide wire inserted through the catheter.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, the evidence insufficient to determine the effects of the technology on health outcomes. For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, the evidence insufficient to determine the effects of the technology on health outcomes.

CODING

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

- 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)

RELATED POLICIES

Not applicable

PUBLISHED

- Provider Update, November/December 2018
- Provider Update, January 2018
- Provider Update, January 2017
- Provider Update, August 2015

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