Medical Coverage Policy | Electromagnetic Navigation Bronchoscopy

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 11|21|2017

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 and 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.

Electromagnetic navigation bronchoscopy is considered not medically necessary for the placement of fiducial markers.

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

BACKGROUND
ENB uses computed tomography (CT) scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. Overall, data are insufficient to determine the risks and benefits of ENB compared with standard approaches to diagnose peripheral lesions.

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography (CT) 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 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.

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 them; none of the methods are ideal for safely and accurately diagnosing malignant disease. 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 24% 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. 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.

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.

Overall, data are insufficient to determine the risks and benefits of ENB compared with standard approaches to diagnose peripheral lesions and enlarged mediastinal lymph node(s), as well as the placement of fiducial markers. The data are also insufficient to identify which patients might benefit from ENB. Thus, use of this technology is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not medically necessary:

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, January 2018
Provider Update, January 2017
Provider Update, August 2015

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