Medical Coverage Policy | Electromagnetic Navigation Bronchoscopy

EFFECTIVE DATE: 01|01|2020
POLICY LAST UPDATED: 08|24|2021

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
Medicare Advantage Plans and Commercial Products
When flexible bronchoscopy alone, or with endobronchial ultrasound, are considered inadequate to accomplish the diagnostic or interventional objective, electromagnetic navigation bronchoscopy (ENB) may be considered medically necessary to:

- establish a diagnosis of suspicious peripheral pulmonary lesion(s) or
- place fiducial markers within lung tumor(s) prior to treatment

Medicare Advantage Plans
Electromagnetic navigation bronchoscopy is not covered for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not covered above, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Electromagnetic navigation bronchoscopy is not medically necessary for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not covered above, 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.

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. Endobronchial ultrasound 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 electromagnetic navigation bronchoscopy. Electromagnetic navigation bronchoscopy 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 electromagnetic navigation bronchoscopy 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. Also, 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 nodes who receive ENB with flexible bronchoscopy, the evidence includes a randomized controlled trial and observational studies. The relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. There is less published literature on ENB for diagnosing mediastinal lymph nodes than for diagnosing pulmonary lesions. One randomized controlled trial identified found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration than with conventional transbronchial needle aspiration. EBUS, which has been shown to be superior to conventional transbronchial needle aspiration, was not used as the comparator. The randomized controlled trial did not report the diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input is not generally supportive of a clinically meaningful improvement in net health outcome. Mediastinal lymph nodes diagnosis was an early indication for ENB which has been largely replaced by EBUS. One could consider it in the uncommon scenario in which linear EBUS is not available and the patient is already having an ENB procedure for a peripheral nodule. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

The following codes are covered:

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)

There is no specific CPT code for electromagnetic navigation bronchoscopy when used for the diagnosis of mediastinal lymph nodes; therefore, providers should report this service with an unlisted procedure code.

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, October 2021
Provider Update, November 2020
Provider Update, May 2020
Provider Update, November/December 2018
Provider Update, January 2018

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