Medical Coverage Policy | Electromagnetic Navigational Bronchoscopy

EFFECTIVE DATE: 01|01|2020
POLICY LAST UPDATED: 08|23|2022

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 be biopsied 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 addressed above, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 addressed above, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

Lung cancer is the leading cause of cancer-related death in the U.S., with an estimated 236,740 new cases and 130,180 deaths due to the disease in 2022. The stage at which lung cancer is diagnosed has the greatest impact on prognosis. Localized disease confined to the primary site has a 60% relative 5-year survival but accounts for only 22% of lung cancer cases at diagnosis. Mortality increases sharply with advancing stage and metastatic lung cancer has a relative 5-year survival of 6%. In addition to tumor stage, other factors such as age, sex, race/ethnicity, and performance status are independent prognostic factors for survival in patients with lung cancer. The average age at diagnosis is about 70 years and most people diagnosed with lung cancer are 65 years of age or older. The lifetime risk of lung cancer is approximately 1 in 15 for men and 1 in 17 for women, with an increased risk in people who smoke. Rates of lung cancer have been dropping among men over the past few decades, but only for about the last decade in women. Black men are about 12% more likely to develop lung cancer compared to White men, although Black men are less likely to develop small cell lung cancer when compared to White men. Among women, the rate of lung cancer is about 16% lower for Black versus White women.

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 RCT and case series. 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 RCT identified found

higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration than with conventional transbronchial needle aspiration. Endobronchial ultrasound, which has been shown to be superior to conventional transbronchial needle aspiration, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following codes are considered medically necessary for the conditions listed in the policy statement above:

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 2022
Provider Update, October 2021
Provider Update, November 2020
Provider Update, May 2020
Provider Update, November/December 2018

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